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Guidelines for STD Control Program Operations

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GUIDELINES
FOR
STD CONTROL PROGRAM OPERATIONS

October, 1985

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control
Center for Prevention Services
Division of Sexually Transmitted Diseases
Field Operations Section
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FOREWORD

For some time the growing diversity of contemporary STD control has prompted project directors and program managers to seek clarifications of national program direction and expectations, realizing that both systems and individuals in STD control need to work in concert and need to be held accountable for the quality of their performance. In October 1984, a group of senior level Public Health Advisors convened to work with the Division of Sexually Transmitted Diseases (DSTD) headquarters staff on this project. This guideline document is the result.

The Guidelines in this document recognize that while areas of the country must differ in their approach to STD control because of unique political settings, populations, and STD problems, there are certain basic program management requirements are common to all. This document includes standards that address these requirements. The standards set forth are expectations considered as criteria for measuring professional performance, management effectiveness, and program excellence. They focus on the common management requirements, yet recognize that what is inherently "right" for one area may not be totally applicable to another. In addition, the standards allow flexibility in setting priorities and permit the program manager to establish quantifiable program objectives.

The guidelines are composed of two parts. The first includes a description of the various components necessary for each STD program to be effective. All components are further divided into subunits, each with standards of program performance. This part is divided into discrete subject matter sections to facilitate updating that will occur periodically and for inserting additional sections that may become necessary. The second section, or Appendices, includes samples of process performance standards, quantitative outcome expectations for STD intervention activities, formulas for computing selected intervention indices, selected references relating to Federal agencies, statutes, and regulations that have a bearing on STD control, and a summary of STD control program operations standards that appear throughout the guideline document.

Our sincere expectation is that these guidelines will be universally applied by STD control programs and will assist State and local health departments reach the 1990 Objectives for the Nation.

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I. INTRODUCTION

These guidelines consider various aspects of the sexually transmitted disease (STD) intervention process and are intended to assist local, State and federal program management develop or modify control procedures in a variety of settings. STD control programs exist in highly diverse social and health settings and there are differences in resources and services among the many project areas in the United States. These differences include the mix of preventable diseases and health conditions, the range of preventive health services available, and the amount of financial resources available to provide STD services. Thus, while no inherently "best" STD control program exists for all settings, certain qualitative and quantitative expectations may be established that represent reasonable standards needed for defining an acceptable level of disease intervention effectiveness.

The standards in this document have been designed to permit quantification of objectives by the program manager. They have also been designed with the flexibility necessary for setting priorities and for adapting to budgetary realities. Some standards, however, because of their intrinsic importance to STD intervention on a nationwide basis, require consistent application throughout the country.

Sexually transmitted disease intervention includes those activities which minimize the adverse health effects from any of the numerous infections and syndromes that comprise this public health problem. The goal of interrupting the natural course of STD in an individual or a community is to reduce disease incidence and duration and, thus, disease complications and their attendant costs.

Different disease intervention activities, such as clinical services, education, screening, interviewing and sex partner tracing can reduce the effects of STD. At the same time, effective STD control efforts must be appropriate to the special populations, disease problems and political settings of each program. Thus, the design of each STD control program will be somewhat unique and cannot be transferred directly from one setting to another.

STD control programs must establish priorities, examine options, calculate resources, evaluate the demographic distribution of the diseases to be controlled, and adopt appropriate strategies. *The success of the program depends directly upon how well program personnel carry out specific day-to-day responsibilities in implementing these strategies which will interrupt disease transmission and minimize the long-term adverse health effects of STD.* Quality assurance systems[1] are necessary to ensure these outcomes.

STD control program management must possess accurate information about the performance of individuals and control components. This information is essential to correctly interpret events and make appropriate policy decisions that ensure program success. Establishing and maintaining an effective quality assurance system requires:

1. the careful development of program objectives;
2. the clear communication of individual performance requirements and expectations;
3. a clear program-wide understanding of the specific outcome and process evaluation targets;
4. the logical assignment of responsibilities to various organizational levels;
5. the detailed design of data collection forms and procedures; and
6. the designation of time periods for reporting and analyzing information.

At the outset, two standards are necessary and appropriate for an STD control program.

Standards

- A quality assurance system for all appropriate components that support disease intervention is established and maintained.
- Acceptable levels of productivity from each control component, and the qualitative standards of performance expected to produce them, are clearly specified by program management.

NOTE: Education is an integral part of nearly every operational component of an STD control program. The behavior of patients and the public as well as the performance of STD program staff and various health service providers have potential impact on disease intervention; as a result the program has a major responsibility to employ educational strategies which positively influence these behaviors. These strategies and standards are outlined in detail in "Guidelines for STD Education."

Each program area needs to identify the the extent of its STD problem. This clarification should include descriptions of the incidence[2] and prevalence[3] of the diseases and their complications by area and population group. The adverse health effects of STD generally will be greatest for specific groups in specific geographic areas. Similarly, disease transmission is not equally distributed throughout the infected population; studies have

[1] Quality assurance system—a system to achieve and maintain performance accountability for all staff who are responsible in any way for the success of disease intervention activities.

[2] Incidence—the number of cases of a disease or condition that occur within a specified period of time in a specific geographic location or in a particular segment of the population.

[3] Prevalence—the number of cases of a disease or condition existing at a given point in time in a specified geographical location or in a particular segment of the population.

shown that there are important transmitter subgroups. To successfully focus control efforts on the correct subgroups requires a system for maintaining clear demographic and disease rate data.

Standard

- A data collection system is established and maintained to provide current data for operational decision making.

II. PROGRAM MANAGEMENT

PROGRAM PLANS

STD program plans are elaborated in documents periodically prepared by State and local health agencies and annually in the CDC project grant application. Careful consideration should be given to the organization and contents of such documents because each has the potential to influence decisions about resources needed for program operations. Plans should be current, consistent, realistic, and address the three levels of factors that impact upon disease intervention.

Primary level factors are those over which the program can exert direct influence, e.g., the quality of clinical services and disease intervention outreach activities.

Secondary level factors are those over which the program has indirect influence, e.g., the behavior of patients and the performance of health service providers who participate in initiatives such as screening, morbidity reporting, and serologic reactor notification.

Tertiary level factors are those which involve individuals or groups who are beyond the program's purview, but whose behavior affects disease intervention. Thus, for example, assertive STD educational outreach efforts may be necessary to reduce the congenital syphilis morbidity among high-risk populations, such as undocumented aliens, who commonly do not seek prenatal care.

OBJECTIVES

STD programs set three types of objectives: *outcome*, *impact*, and *process*. An *outcome objective* is a target quantitative measurement of a health problem at some future date which the program can and should reach. Outcome objectives are usually to reduce the morbidity or adverse health effects of STD in a certain population or locality over a specified period. Outcome objectives should be framed in accordance with the 1990 Objectives for the Nation.* Examples of such outcomes objectives are: "By 1990, the reported incidence of gonococcal pelvic inflammatory disease in the State will not exceed 60 cases per 100,000 females;" and "By 1990, every junior and senior high school student in the State should receive accurate, timely education about STD."

Impact objectives are statements of the program's intended accomplishments in the immediate future, usually during a one-year budget period or by some specified point within the budget period. They should be very specific, quantified, measurable, and achievable within the proposed time and setting. An impact objective expresses the measurable yield calculated to result from various complementary disease intervention activities. The 1990 Objectives for the Nation define the mission of STD control in terms of preventing disease and complications; therefore it is appropriate to use these concepts in expressing impact objectives. For example, "During FY 19__ the program will prevent 400-500 cases of gonococcal PID as the result of screening, female sex partner referrals through the counseling of male patients, and direct disease intervention outreach by D.I.S. staff" or "...prevent 100-200 cases of syphilis through serologic reactor followup and D.I.S. outreach applied to cases who volunteer, are privately reported, and are identified through program efforts" or "...report no instances of syphilitic stillbirth or congential syphilis in newborns that were preventable through program action." These calculations are feasible for both examples because there are ample data* which project the percentage of persons who will develop PID without therapy and syphilis without preventive treatment. Because they reflect the collective result of various activities, only one or two impact objectives are needed for any particular disease entity or program component.

Process objectives are action statements that express either the level of quality or the level of output expected in the performance of various activities by different program components. Such process objectives in combination are essential to reach an impact objective. The distinction between a process objective and an impact objective is how one answers the question, "to what end?" Process objectives express the expected results from individual, carefully targeted activities; they are not ends in themselves, but rather combine with other process objectives to produce the yield needed to achieve a specific program impact objective. In terms of sequence, however, the target figure which appears in an impact objective is determined after setting all of its related process objectives, summarizing their expected productivity, and calculating their combined projected yield.

Examples of process objectives related to a level of quality might include: "During FY 19__, a minimum of 80 percent of all STD field investigations undertaken are conducted such that all actions taken conform to the pro-

*Department of Health and Human Services: Promoting health/preventing disease; objectives for the nation. U.S. Government Printing Office, Washington, D.C., Fall 1980.

*10%-17% of females with gonorrhea will develop PID (Eschenback DA, Holmes KK: Acute pelvic inflamatory disease: current concepts of pathogenesis, etiology, and management. Clin Obstet Gynecol 18:36, 1975); about 65% of noncultured female sex partners to gonorrhea will be infected and about 25% of culture negative, preventively treated female sex partners to gonorrhea will be infected (Wiesner PJ, Thompson SE: Gonococcal Diseases. DM :XXVI:11, 1980; Judson FN, Wolf FC: Tracing and treating contacts of gonorrhea patients in a clinic for sexually transmitted diseases. Public Health Rep: 93:460, 1978; and Mardh PA: Chapter 69, Bacteria, chlamydiae, and mycoplasmas, in Sexually Transmitted Diseases, Holmes K, Mardh P, Sparling F, and Wiesner, P (eds), New York, McGraw Hill, pp. 829); up to 36% of females with chlamydia will develop PID (Mardh PA et al: *Chlamydia trachomatis* infection in patients with acute salpingitis. N Engl J Med 296:1377, 1977); and 30% of sex partners to infectious syphilis will develop disease (Schroeter AL, et al: Therapy for incubating syphilis: effectiveness of gonorrhea treatment. JAMA 218:711, 1971).

cess performance standards[4] of the program;" or "During FY 19__, at least 90 percent of all STD clinic patients will receive care and treatment that conforms to the established protocol."

STD program process objectives concerned with the level of output are of two basic types: (1) *disease intervention*; and, (2) *behavioral education*. As an example, consider the impact objective—to prevent 400-500 cases of gonococcal PID. Some selected *disease intervention process objectives* that would relate to it might include:

During the next fiscal year,

- Screen 150,000-175,000 women for gonorrhea;
- Maintain a positivity rate in excess of 4.5 percent;
- Assure 80-85 percent of gonorrhea screening positives are treated within seven days of test and 95-97 percent are treated within 14 days; and
- Assure that a disease intervention index of .80-.90 results from the interviewing/counseling of male gonorrhea patients.

Some applicable *behavioral education process objectives* for the fiscal year might include:

- Through selective monitoring with educational followup, assure that 80-90 percent of all privately reported cases of uncomplicated gonorrhea have been treated with recommended therapies at the time of diagnosis;
- Increase from 25% to 40% the percentage of clinic male gonorrhea patients who bring at least one identified sex partner to examination without the assistance of a D.I.S; and
- Maintain at 90% the percentage of target hospital GPID patients who receive adequate therapy, including a followup oral regimen, without health department intervention.

The subject of behavioral education process objectives and education impact objectives is discussed in greater detail in the document, "Guidelines for STD Education."

Heretofore, it has been common to consider various procedural action steps (e.g., "establish a system to...," "hire staff to...," "meet with hospital officials to...," "meet with local boards of education to...") as process objectives. Such steps, like process objectives, are means to a more significant end; however, they do not express a level of quantity and so fail to meet the definition of a process objectives as set forth in this document. Therefore, action steps of this nature are to be considered methodology and should be part of either the plan of operation outlining precisely how different process and impact objectives will be met or part of the evaluation plan if they appropriately fall into this category.

[4]Process performance is the execution of required skills and techniques in carrying out the individual tasks of various program activities. Process performance standards are a written set of specific expectations that describe the quality (depth of analysis, thoroughness of preparation, precision of timing, competence of delivery, and conscientiousness of follow through) required in applying these skills and techniques. A prototype set of process performance standards appears as Appendix A.

Standards

- **Outcome objectives** address the 1990 Objectives for the Nation.
- **Impact objectives** address each program component and are clearly stated, realistic, specific, measurable, and time-phased.
- **Process objectives** are realistic, specific, measurable, time-phased, and clearly relate to the achievement of program impact objectives.

OPERATIONAL PLAN

Periodically, an STD program must carefully review its operational plan for achieving various outcome objectives. This plan should relate to each impact and process objective and detail specifically how various activities will be conducted to achieve the expected results which the objectives express. As new impact objectives are established, or as current ones are revised with different levels of expected achievement—such as when the program subsequently fails to meet established process objectives and/or an established impact objective that were realistic in terms of resources and theoretical capabilities—the operational plan needs to be amended to reflect any new or altered methods.

Standards

- The operational plan clearly explains how the impact objectives and the process objectives of the program will be achieved.
- The operational plan is revised when problems result in unsatisfactory achievement of any established impact or process objectives or when improved methods are devised to pursue particular objectives.

EVALUATION PLAN

The evaluation plan must describe how the program will regularly monitor progress toward the achievement of each objective. It details systems that generate information, allowing management to compare results against intended objectives and assess the quality of program performance. Evaluation must be an integral part of the STD control process and must provide continuous feedback to the program. The evaluation plan must include the procedures for gathering information and the instruments for reporting it to program management. Systems to monitor program implementation, efficiency, effectiveness, and impact are critical responsibilities of the program manager[5] and firstline supervisor[6]. Program managers naturally have a primary interest in outcome evaluations, which

[5]Program Manager—That person or cadre of persons responsible for establishing STD program goals, objectives, directions, policies, and procedures, accountable for the effective use and development of the essential human resources of the program, and answerable for the overall performance of the program in achieving disease intervention.

[6]Firstline Supervisor—The STD program professional responsible for the orientation, on-the-job training, development, and performance evaluation of D.I.S. and for directing their day-to-day activities to ensure that process performance results in meeting program outcome objectives.

should indicate if there has been progress in STD control and if the policies, strategies or plans of operation need to be revised.

However, managers must also monitor the quality of process performance at each employee level, since such information will help to identify the causes of any problems which are compromising overall program performance. On the other hand, supervisors will maintain a primary interest in process evaluations that measure program and individual efficiency/effectiveness, as well as test the validity of their observations of *how well* people are performing. Evaluation should always be considered during the planning and implementation stages of STD programs or activities. The measurement of how much activity is occurring, how quickly it is happening, and with what quality it is being accomplished is a critical function of any STD control program. In addition, STD programs should establish methods to measure the outcomes produced by the process performance of program staff. Ideally, the evaluations of outcome and process should work in concert to assist with an evaluation of the entire program. To be effective, evaluation plans should first define the objectives to be accomplished, clearly state the methods staff should use to accomplish them, and establish a system for collecting and analyzing the data. Corrective action must be taken promptly as program deficiencies are identified.

Standards

- The STD program establishes and maintains a system for evaluation of its intervention efforts.
- The evaluation plan clearly describes the procedures for gathering outcome and process performance information and the systems for reporting to program management.
- The evaluation plan clearly describes how outcome and performance information are used to provide quality assurance for various program activities.

INTERACTION WITH OTHER AGENCIES

As the clinical spectrum of STD has expanded, it has become obvious that STD programs must develop, cultivate and maintain effective working relationships with a growing network of providers within the health care delivery system. STD programs have recognized the importance of such relationships and many have expanded that portion of their budgets devoted to improving interaction with providers, especially with private physicians and laboratories. The gonorrhea screening initiative demonstrated the importance of maintaining close administrative ties with the family planning, prenatal care, and maternal and child health programs, as well as with public and private hospitals. In some areas these relationships have featured mutually reinforcing efforts, such as STD program referrals for family planning services and STD screening, counseling, and referrals from family planning clinics.

Pelvic inflammatory disease (PID) programs have reemphasized the need for such relationships. For PID initiatives to work, it is critical to have a close liaison with hospital emergency rooms (ER) and outpatient departments, but also, at a higher level, with hospital administrative staff. Most effective STD programs have established liaison positions in which staff carefully review hospital records so that individuals with symptoms or laboratory results suggestive of STD can be quickly identified and followed. Experience has taught programs that they must become more involved with key people in such institutions to influence those parts of the program they do not maintain themselves. Administrators change, as do ER directors, nurse epidemiologists, and key laboratory and clerical personnel. It is essential for STD programs to have active, ongoing interaction with all agencies that have the potential to affect disease intervention outcomes and STD program objectives.

Standards

- The program has a system to assure ongoing interaction with all agencies which can impact on STD control.
- When non-STD health care needs of patients are identified, the program establishes referral arrangements with appropriate service providers that collaborate with the program in STD control activities.

III. GONORRHEA SURVEILLANCE

SCREENING COMPONENT

Through selective screening, gonorrhea control programs must have the ability to identify and bring to treatment individuals who are likely to have a gonococcal infection or its complications. This screening activity is usually limited to women in the childbearing age who are receiving pelvic examinations for any reason. The rationale for such screening is:

1. women with gonorrhea are frequently asymptomatic;
2. most gonorrhea occurs during the early sexually active period; and
3. low-prevalence screening sites represent "true screening" and may serve as an unbiased indicator of disease trends in the community.

Standards

- The project area supports and promotes a system for the detection of asymptomatic gonococcal infections among women of reproductive age.
- The program maintains a system to assure that treatment is provided to infected women identified through this screening process.
- The program maintains a mechanism for assessing disease trends among sexually active women not seen in STD clinics to compare with the trends from public STD clinics.

QUALITY ASSURANCE

Operational quality control is a vital element of gonorrhea surveillance activities. The quality control process for a gonorrhea screening program is classic quality assurance—it produces process observation findings from actual on-site assessments of program activities. These findings can then be compared with and used to help explain objective output data. Operational quality control visits should be conducted at least annually and more frequently when assessment of output data suggests a significant variation in process performance. Appendix B is a guide that can be used for such visits. These visits should be more than a series of questions asked of staff at the screening facility. The necessary information should be gathered by direct observation. The person performing the quality control visit must function as a problem identifier and strengthen liaisons between the program and the health care facility.

Two additional elements also are necessary for an effective quality control system for gonorrhea surveillance. The first is an efficient mechanism to distribute culture media to participating facilities. This mechanism should provide each screening facility with adequate amounts of fresh media and monitor the number of plates distributed. The second element involves laboratory standards that include inventory, usage and check testing of media, quality control of reagents, correlation of results of gram stain smears and urethral cultures in men, etc.

Standards

- The gonorrhea screening component includes:
  - a system to regularly analyze screening results by individual provider sites;
  - periodic, documented on-site observations to assure all procedures are functioning at an optimum level;
  - periodic, documented firsthand observations of the performance of the culture delivery system; and,
  - periodic data produced by laboratory quality control procedures.

COST-EFFECTIVENESS DECISIONMAKING

The prevalence of gonorrhea varies widely by geographic area, time, and patient populations. The volume and yield from screening sites should therefore be constantly reviewed to determine overall cost-effectiveness by comparing current data with data from previous year's screening activities. Efforts should be made to increase the overall yield from screening activity, redirecting screening resources if appropriate. Decisions to alter or discontinue the support of screening at an individual provider site must be based upon the yield of new infections identified compared to the current level of resources expended. However, some low prevalence sites that see women of childbearing age, i.e., family planning clinics, may represent stable "true" screening and can be extremely valuable when assessing disease trends in the community. Though not currently cost-effective from a disease detection standpoint, cooperative providers who historically see various STD should be encouraged to continue culture testing at their own expense or at a level which does not utilize program-supported media delivery services. One alternative to logistical support systems would include establishing drop-off points to enable the provider to pick up and deliver media. Others would be the utilization of hospital and commercial laboratories and formal training for providers to read their own cultures.

Standards

- Each program will establish a data system which allows for the analysis of screening data both by individual site, type of provider, and in the aggregate.
- All decisions affecting the scope and composition of the gonorrhea screening program are based upon the output data *and* the documented firsthand observations of process quality at individual sites.

FOLLOWUP SCREENING

Screening efforts should be maintained at a high level in those provider sites in which the efforts are cost-effective and among those populations who, based upon area of residence and other demographic information, are identified as high-risk. In addition, sites that treat patients with a positive gonorrhea culture should assure these individuals receive followup cultures. A patient who is inadequately treated, who fails to take the prescribed medication, or who has a drug resistant strain of gonorrhea, quite likely represents a breakdown in disease intervention procedures.

Standard

- Each health care provider offering treatment is systematically encouraged to reculture treated female gonorrhea patients 3 to 7 days after completion of therapy.

IV. RESISTANT GONORRHEA

INTRODUCTION

Reduction of the sensitivity of any organism to available therapy can have devastating consequences on STD control efforts and adversely affect the management of individual infected patients. Since it was introduced into the continental United States in 1976, penicillinase-producing *Neisseria gonorrhoeae* (PPNG) has remained one of the highest national STD program priorities. If PPNG or other non β-lactamase-producing but resistant organisms, such as chromosomally mediated resistant *Neisseria gonorrhoeae* (CMRNG), were to become endemic in the United States, recommended treatment schedules would be ineffective; the number of patients with complications would increase and treatment would become much more costly.

Efforts to control PPNG outbreaks since 1976 and CMRNG outbreaks since 1983 in the United States have produced the following observations:

1. Core groups of key disease transmitters were identified by analyzing patient sociodemographic data. For example, prostitutes appeared to play a major role in the PPNG outbreaks in Los Angeles, New York City, and Miami;
2. Successful control efforts have resulted from a combination of good surveillance and reporting systems; rapid, high-quality disease intervention outreach; culturing of symptomatic males in addition to the Gram stain smear within target populations; and the use of spectinomycin as initial therapy within a target population; and,
3. Persons with a recent history of foreign travel (U.S. civilian and military, and foreign nationals) continue to import PPNG into the country.

STD programs will continue to face the challenges of new or different strains of disease. Each program area must be prepared to confront emerging outbreaks with speed, vigor, and the highest possible quality application of appropriate disease intervention outreach procedures.

Standard

- The STD program establishes and maintains all the surveillance, laboratory, and disease intervention outreach systems necessary to identify and abort any outbreaks of PPNG, CMRNG or other resistant strains of *N. gonorrhoeae.*
- The program establishes an incidence threshold for recommending that all gonorrhea patients be routinely treated with recommended therapy for resistant organisms.

LABORATORY IDENTIFICATION

PPNG or other resistant strains cannot be clinically differentiated from other strains of gonorrhea. Diagnosis currently requires laboratory identification of a viable gonococcal organism for both penicillin sensitivity and β-lactamase production which cannot be obtained from a Gram stain smear. A surveillance program must ensure that all laboratories processing cultures for the detection of gonorrhea are analyzing at least positive test-of-cure cultures for β-lactamase production and sensitivity to other antibiotics. Rapid reporting by the laboratory (preferably by telephone) to the STD program is crucial to identifying disease intervention opportunities. Followup of infected individuals, their sex partners, and relevant others, must occur immediately to ensure that patients receive adequate therapy and to minimize the opportunities for PPNG to spread.

Standards

- The STD program ensures that the following categories of patients receive both an anogenital culture for gonorrhea, which includes testing for penicillin resistant and β-lactamase producing organisms, and appropriate therapy for resistant organisms:
  - sex partners and/or clusters to a PPNG or CMRNG case;
  - patients with a history of travel (within 60 days) to foreign or domestic areas of high-prevalence;
  - treatment failures confirmed by positive laboratory results.

NOTE: Most major outbreaks involving resistant gonorrhea have identified prostitutes as core transmitters. In outbreak situations, therefore, consideration should also be given to providing appropriate therapy for prostitutes and for patients who claim exposure to prostitutes.

INTERVIEWING/COUNSELING AND FOLLOWUP

State and local STD control programs should not only establish process performance standards for PPNG and CMRNG interviewing/counseling and investigative activities, but should also be able to continuously monitor and evaluate these activities. In addition to utilizing appropriate interviewing approaches, all necessary and available resources should be used to expedite the examination of sex partners. It is also reasonable and necessary to expect the test-of-cure rate to approach 100 percent, with any exceptions well documented and reasonable. Outcome expectations for interviewing/counseling and investigation should be maintained at the highest level possible (see General STD Intervention Outcome Expectations, Appendix C).

Standard

- The STD program has a system which ensures that the sex partners and clusters of PPNG and CMRNG patients are rapidly identified, medically evaluated, appropriately tested and adequately treated.

V. CHLAMYDIA CONTROL ACTIVITIES

INTRODUCTION

Infections caused by *Chlamydia trachomatis* are now recognized as the most prevalent and among the most damaging of all STD seen in the United States today. The estimated incidence is 3 million infections annually. Men, women, and infants are affected, but women bear an inordinate burden because of their increased risk for adverse reproductive consequences. In women, chlamydia can cause urethritis, cervicitis, endometritis, salpingitis, and PID (a frequent cause of infertility and ectopic pregnancy). An estimated 5 percent of pregnant women are infected with *C. trachomatis*, which can be transmited to their children at birth and which causes approximately 75,000 cases of infant conjunctivitis and 30,000 cases of infant pneumonia annually. In men, chlamydia is the leading cause of nongonococcal urethritis, which may result in male infertility.

STD control programs must begin to define and implement efforts to control chlamydia. At present, no additional grant funds have been appropriated at the Federal level to implement such programs. However, this does not preclude areas from establishing meaningful surveillance, plus systems of testing, treatment and interviewing/counselling. Many areas of the country have begun utilizing existing resources which have become available because of shifts in priorities, or new State or local funds allocated for these purposes. Initial activities should be directed toward surveillance, patient management, and prevention.

SURVEILLANCE

State STD control programs should be in a position to describe the magnitude of the disease problem, trends, and the distribution of chlamydial infection within the population. To this end, the establishment of chlamydia and its surrogates (i.e., nongonococcal urethritis and nongonococcal mucopurulent cervicitis) as a reportable STD should be a high priority. Reporting by name will also enhance sex partner referral and other disease intervention outreach activities. In most areas, this will require a change in the health department regulations, but in some it will mean revising an existing statute.

Standard

- The STD control program establishes a surveillance system to identify the extent and trend of *C. trachomatis* infections within its jurisdiction.

PATIENT MANAGEMENT

When cultures for *C. trachomatis* are available, definitive results will obviously determine therapy. Because of the cost of cultures, however, presumptive diagnosis dictated by an established high risk profile must also be used to guide treatment approaches. Based on current data, high risk* patients who fall in the following groups should be treated immediately with appropriate therapy for both *C. trachomatis* and *N. gonorrhoeae* infection unless local or individual circumstances dictate otherwise. These groups include:

Those with symptomatic syndromes

Nongonococcal urethritis
Mucopurulent cervicitis
Urethral syndrome/dysuria frequency
PID
Epididymitis

Asymptomatic sex partners

Individuals exposed to patients with any of the above symptomatic syndromes should be evaluated for STD and treated with an appropriate regimen for chlamydial and gonococcal infection.

Standard

- The STD program establishes a high risk profile which delineates those patients who should receive dual therapy to cover both chlamydial and gonococcal infections.

PREVENTION

Patient counseling is an integral part of the effective management of chlamydial infection. Counseling should be designed to influence specific behaviors which will contribute to successful therapy, disease intervention outreach, and the prevention of infection. Patient handouts designed for easy comprehension are an efficient means of providing the patient with basic information. These messages, especially those dealing with treatment compliance and avoiding "unprotected" sexual activity until therapy is completed, should be reinforced by STD clinicians and private practitioners. Communication should be with the individual patient and should provide him/her an opportunity for feedback.

All high risk patients targeted for dual therapy who are seen in STD clinics should be counseled by STD clinic staff to refer for medical evaluation all of their sex partners during the 30 days prior to onset of their clinical symptoms or their date of clinical evaluation. Patients diagnosed with presumptive PID need more extensive attention than clinic staff normally can provide and usually require direct assistance in the referral of sex partners. Therefore, women with presumptive PID should receive an interviewing/counseling session from a Disease Intervention Specialist (D.I.S.).

*Teenage males, females < 30, and patients with multiple sex partners, who are seen in STD clinics.

Standards

- The STD program establishes a system which ensures all high risk patients seen in STD clinics are counseled to refer their sex partners for medical evaluation.
- The STD program establishes a system which ensures that each PID patient receives an interview/counseling session by a D.I.S.

VI. PELVIC INFLAMMATORY DISEASE

INTRODUCTION

The operational definition for PID is: (a) a clinician's diagnosis of PID; or (b) upper genital tract symptoms or signs (i.e., abdominal pain, adnexal tenderness, etc.) when other diagnoses are judged unlikely. In addition, one or more of the following must be present: (a) positive endocervical or anal culture for *N. gonorrhoeae* or *C. trachomatis*, (b) typical gram-negative intracellular diplococci (as determined by an experienced microscopist) on an endocervical specimen, or (c) gonococcal or chlamydial or nongonococcal urethritis infection in a current established male sex partner.

PID SCREENING

Many patients with acute PID attend hospital emergency rooms or hospital walk-in clinics rather than STD facilities because of the severity of their illness; usually they are not aware that their infection is sexually transmitted. Their clinical assessment should include a culture for *N.gonorrhoeae* and *C. trachomatis*. Every positive culture from an ER setting should be followed as a probable PID case.

Standards

- A system to culture and follow identified PID is established and maintained.
- Ensure that recommended procedures are observed, and possible cases are screened and followed by regularly visiting PID screening sites.

THERAPY FOLLOWUP

Response to PID therapy is critical to recovery and must be evaluated to determine if the patient is better. The logical site for this assessment to occur is the original testing/treating site since the patient's medical records are most available at that location. It can occur, however, in a hospital outpatient clinic, a physician's office, or at the health department. The evaluation should include a review of persistent symptoms and should seek to determine how well the patient has taken prescribed medications. Ideally, a bimanual pelvic examination should be performed. **There is the potential to expend significant amounts of program effort in insuring that patients receive follow-up examinations. It is therefore important for program management to establish its priorities and to develop a workable system which includes a minimum of D.I.S. involvement.**

Standard

- The program establishes a system to ensure that patients diagnosed with PID are assessed within 5 days of their initial visit.

TEST-OF-CURE FOLLOWUP

Each patient should receive a test-of-cure (TOC) 3 to 7 days following completion of their 10-day therapy regimen. This evaluation should also include a history, another bimanual examination, and a post-treatment culture for any pathogen (e.g., *N. gonorrhoeae* and *C. trachomatis*) isolated before therapy. The STD program should ensure that both the patient and the treating facility are aware of the importance of the TOC evaluation.

Standard

- The program establishes a system which ensures that all patients diagnosed with PID and those providing care for them are aware of the need to have a test-of-cure culture performed within 3 to 7 days following completion of therapy.

PID PROGRAM LIAISON

As stated earlier, PID initiatives have reemphasized the critical need for programs to establish close liaison with their hospital emergency rooms and outpatient departments if this initiative is to be effective. This is no longer an option, but an operational necessity, since the initiative has been expanded to encompass PID caused by chlamydia as well as gonorrhea. In many areas, D.I.S. now will be unable to effectively meet their primary disease intervention responsibilities with all priority conditions and still perform the time consuming tasks historically required to reach a PID patient. Therefore, staff from emergency rooms and outpatient departments must be persuaded to play an increasingly active role in this process.

One-way communication, e.g., from the hospital to the program's liaison, usually will not be sufficient to ensure program success. Quite often the failure of emergency room and other medical staff to cooperate with the PID followup program results from their lack of knowledge about the process. Therefore, a feedback system is critical to stimulate improved performance from these providers. With increased interest, problems such as inaccurate or insufficient identifying information may be reduced or eliminated.

Standards

- The program establishes a cooperative system in which hopitals and other PID surveillance sites assume increasing responsibility to conduct initial PID patient counseling, search records, verify laboratory results, ensure medical assessment and test-of-cure referrals, and, *especially*, to make prompt referrals of patients to the health department for an interviewing/counseling session by a D.I.S.

- The program establishes a system to provide regular feedback to hospitals and other PID surveillance sites about cases identified, including results of case investigation activities.

PID INTERVENTION ACTIVITY

PID programs should establish an active surveillance system designed to ensure timely identification of possible cases. Once identified, activity should be focused upon competent and timely medical care, counseling of PID patients to comply with therapy, and other behavioral recommendations necessary to resolve the infection. The value of these efforts is seriously diluted unless there is a disease intervention outreach component of PID control, i.e., the identification and rapid treatment of the patient's infected sex partners. Thus, each STD program must assertively apply high quality disease intervention outreach activity for as many patients as possible presenting with symptoms/syndromes of PID. However, disease intervention outreach results can be compromised if there is a one week or greater time lag between the PID diagnosis and the interviewing/counseling session, especially if the provider of care performed *no* counseling for the patient. Typically, serious time lags occur that compromise PID intervention outreach results when D.I.S. are forced to perform interviewing/counseling sessions in the field, as well as to conduct all of the background work (i.e., record searching, verifying laboratory results, etc.) and expend the locating effort prerequisite to that activity. The operational ideal is to establish systems whereby the diagnosing facility ensures each PID patient is properly treated (with dual therapy), is initially counseled, is appointed for followup, and is referred *immediately* to the health department for an interviewing/counseling session.

When disease intervention outreach is applied for PID patients, two points are crucial and should be considered in each instance. These are:

1. The motivations employed with PID patients should include both the personal avoidance of reinfection as well as the health risks to others and the need, because of the frequently asymptomatic nature of the disease in their sex partners, to ensure that they are discussed and examined; and,
2. Most PID patients will need active program outreach to refer their sex partners because even if these partners are infected they may be free of symptoms and therefore may resist medical examination.

Standard

- The program should assertively pursue the ideal of a PID initiative where D.I.S. involvement in each case begins with an interviewing/counseling session conducted with a patient successfully referred to the clinic by a diagnosing facility.
- The program establishes and maintains a system which ensures that the infected sex partners of PID patients are rapidly identified and treated.

VII. SYPHILIS SURVEILLANCE

THE CENTRAL REGISTRY

An essential activity of the syphilis control component of any STD program is selective screening which identifies individuals who have untreated syphilis from among those who have a suggestive serologic test for syphilis (STS). The screening tools presently available are several recommended nontreponemal serologic blood tests (VDRL, RPR, USR, RST). Treponemal serologic tests (FTA-ABS, MHA-TP, HATTS) are not recommended for screening. They are to be reserved for distinguishing a valid positive reaction caused by syphilis from a false-positive nontreponemal reaction or for confirming a clinical impression of syphilis in very early cases where nontreponemal tests are nonreactive. When an STS is reactive, the medical laboratory performing the test must be required by statute, ordinance or regulation to submit the report to the State or local health department. The STD control program should keep reactor reports for specified periods of time in a central registry.

The central registry is the administrative heart of a syphilis surveillance operation. The efficiency of its operation determines whether a syphilis surveillance activity is an asset or a liability to the efficiency and effectiveness of disease intervention outreach activities. How well the central registry operates is determined by the performance of the employees, the machinery used, and the procedures selected to guide the operation. Obviously the employees who use the machinery and follow the procedures are essential factors for success. Their selection, training and supervision—plus periodic quality assurance of performance—are major management responsibilities. The registry itself may be manual, mechanical, or computerized. While these represent an ascending order of technological sophistication, they do not necessarily represent an ascending order of efficiency. All systems will depend on human judgment for final decisions regarding who is or is not to be followed by the program to obtain a medical disposition.

Standard

- The program has an efficient, up-to-date central registry which includes the following:
  - Patient name
  - Last address
  - Age or birth date
  - Race/ethnic origin
  - Sex
  - Diagnosis
  - Date and result of all positive tests
  - Treatment date(s) & regimen
  - Health provider of record

CRITERIA FOR FOLLOWUP AND CLOSURE

Many reactive STS reports received in the central registry are closed administratively, because the suspect has a negative treponemal serologic test result, or because age and serologic titer are determined not to justify followup. The remaining reactive tests should be promptly searched in the central registry to determine if the patient has a previous record. Patients without a previous record, or whose current test results suggest a possible reinfection, need to be referred for further medical evaluation and possible treatment. Programs must determine which patients to follow and methods to be used (e.g., physician query, patient motivational letter, phone, or field investigation), and the individuals responsible for the method chosen.

Reports of reactive STS which are assigned for field followup and referral are high priority. These reports indicate that the suspect might have infectious disease, or that infectious disease might be prevented as a result of following that particular reactive test, e.g., a prenatal reactor.

Standards

- The program has written criteria that clearly state which reactors are administratively closed (usually because of age, titer, or negative confirmatory test), which reactors will receive followup, the method for doing so, and who has responsibility in each situation. (Appendix D is a sample written reactor criteria in a grid format which is convenient for making rapid determinations, often by staff without sophisticated understanding of positive STS interpretation).
- The program establishes a policy to routinely assess yield from age/titer categories to effectively differentiate between high and low priority STS and to decide which should receive administrative closure.

LABORATORY SURVEILLANCE

In addition to a central registry which identifies individual patients, the program should maintain a log which tracks individual laboratories and which reflects their reporting by date and test result. This log is essential to determine problems/breakdowns in reporting. At least annually (more often if problems occur), each laboratory should be asked to review its reporting procedures and produce the records of positive specimens processed. These records should include patient name, test result, and the date each positive report was submitted to the STD control program.

As noted in the section on PID, information feedback is essential for the consistent appropriate performance and continued cooperation of health providers whose participation is critical to the success of an STD program

component. The program should periodically publish and disseminate reactor reporting and followup results data to the medical laboratories within its health jurisdiction.

Standards

- The program has a legal requirement that all reactive STS are reported.
- The program has a system to monitor reactive STS reporting by individual laboratories.
- The program has a quality assurance system which, either by letter or visitation on at least an annual basis, confirms the reporting performance of all medical laboratories performing tests for STD.
- At least annually, the program distributes summary reactor reporting and followup results data to all medical laboratories.

VIII. STD INTERVENTION ACTIVITY

INTRODUCTION

The overall goals of disease investigation outreach in STD control are to identify the population at increased risk and reduce their chances of developing STD, transmitting it to others, and/or developing its complications. While appropriate screening, diagnostic, education, and treatment services are essential, individual case management and referral services for those at highest risk can help preclude the spread of infection and ultimately control STD in a community. The STD intervention component of the program is designed to meet this need. Such activities are performed by a disease intervention staff who interview/counsel infected patients to ensure the referral of sex partners and others who are potentially infected. This component includes activities that are dependent upon each other for overall success: preinterview preparation, an interviewing/counseling session, postinterview analysis and decisionmaking, the selection of candidates for reinterview and cluster interview, reinterview and/or cluster interview, and initiation, completion and documentation of field investigation activities.

A direct relationship exists between the skillful application of basic disease intervention processes, the outcomes which result, the disease intervention that is achieved, and the ultimate reduction of morbidity. Therefore, STD program management must establish procedures to regularly monitor all disease intervention activities and their yields. First, however, management must define the expectations against which performance and results will be measured. The project grant application and similar planning documents set forth program goals which define the disease intervention outcomes expected and the project objectives expected to be accomplished through outreach activities. Expectations of individual employees are contained in process performance standards, which define the quality of individual effort anticipated from each D.I.S.

Standards

- The program develops and publishes process performance standards for disease intervention outreach activities.
- The program maintains systems to keep management informed of the yield from disease investigation activities.
- The program establishes and maintains a D.I.S. quality assurance system that keeps management regularly informed about the quality of individual D.I.S performance.
- The program maintains a system to ensure that all employees' formal performance evaluations accurately reflect the quality of their performance and the program impact which results from that performance.

NOTE: For more detailed information on D.I.S. performance development and the quality assurance of their performance, consult the CDC publication, "Quality Assurance Guidelines for Managing the Performance of Disease Intervention Specialists in STD Control."

PREINTERVIEW PREPARATION

A successful interviewing/counseling session is the product of numerous factors. High on the list is thorough preparation, because disease intervention opportunities depend on the D.I.S. knowing and skillfully using pertinent, available facts. Advanced preparation is essential for each priority interviewing/counseling session.

Standards

- The program has a system which ensures that before any original interviewing/counseling session, the D.I.S. undertakes a thorough analysis of:
  - available medical records;
  - available historical information pertinent to the current infection;
  - interviewing/counseling and investigative records for evidence of relationships to other known cases; and,
  - information from other D.I.S. staff.

THE INTERVIEWING/COUNSELING SESSION

Successful disease intervention requires that diagnosed patients are cured and remain free of disease, and that all sex partners promptly receive appropriate medical attention. The traditional focus of the STD interview has been to ensure the examination of sex partners. The contemporary STD interviewing/counseling session retains a central focus on sex partner identification, referral and examination, but also encourages patient cooperation in the STD control effort by emphasizing certain individual behaviors designed to avert the unnecessary spread of disease in the future. The rationale for this aspect of the interviewing/counseling session is to promote, through emphasizing the patient's own self interest, responsible health behavior which will interrupt disease transmission and prevent future infection. Patients successfully persuaded to practice such behaviors contribute to the cost-effective operation of the STD control program.

Standards

- To achieve maximum disease intervention, STD interview/counseling sessions are conducted without delay after the case comes to program attention to:
  - clarify to the patient the health department's responsibility for interrupting disease transmission and the department's professional, confidential

methods for ensuring that all sex partners receive prompt examination and necessary treatment;
- give sound justification for discussing detailed specific information about each sex partner or any other persons who need an STD examination;
- positively, but assertively, confront the patient about any evasive behavior that suggests indifference toward curing his/her own infection or which might jeopardize the health of sex partners;
- ensure through tactful persistence that each sex partner at-risk is discussed and then described in the detail necessary to effect the promptest possible examination.
- set conditions of referral whenever it is agreed that the patient will refer a sex partner for examination; provide understandable information to the patient about his/her disease; and,
- counsel on appropriate behaviors to ensure the patient's present disease is cured, that the risk of future disease is minimized, and that, if infected again, the patient will present for medical evaluation and treatment as soon as possible.

POSTINTERVIEWING/COUNSELING SESSION ANALYSIS AND DECISIONMAKING

The STD interviewing/counseling session is but the first step in the continuum of disease intervention involving the examination of sex partners. Disease intervention is achieved when sex partners actually reach appropriate medical attention and receive treatment or preventive treatment. Time is a critical factor in all steps that immediately follow the interviewing/counseling session. The analysis of information exchanged in the session is a worthwhile investment of time that pays dividends in the form of prudent decisionmaking and the most efficient use of carefully targeted D.I.S. resources. Analysis and prudent decisionmaking should continue to guide STD case investigation efforts from this point until formal closure of the case.

Standards

- Immediately after all interviewing/counseling sessions (including reinterviews and cluster interview), the D.I.S. thoroughly:
  - searches for information on sex partners to determine any prior medical or disease intervention records relevant to the present case;
  - reviews standard investigative resources to confirm locating information on all sex partners;
  - analyzes the disease intervention information on identified sex partners and accurately determines probable relationships, possible factual omissions, set priorities for field investigations, and potential avenues to pursue future disease intervention.
  - determines the need for reinterviews and/or cluster interviews or decides to discontinue further activities.

SELECTION OF CANDIDATES FOR REINTERVIEW

Ideally, each original interviewing/counseling session should be performed skillfully enough to identify all of the patient's critical-period sex partners. Program management and involved supervisory personnel should vigorously pursue this ideal by upgrading the performance of D.I.S. staff members to produce superior original interviewing/counseling sessions. Occasions will arise, however, when a clear potential exists to achieve disease intervention through reinterviewing a patient. There will also be instances when, because of the number of sex partners named, the patient needs to refer to a diary or to consult with others to verify identities and locating information; in such instances, arrangements can and should be made for a followup telephone call instead of an in-person reinterview.

Most often when reinterviews are needed, it is because it has become clear that the patient has evaded discussing and/or referring all sex partners during the original interviewing/counseling session . Thus, each reinterview should be carefully justified by the D.I.S. and the firstline supervisor; the extent of preparation should befit the quantity and quality of information available to analyze, the potential importance of the event to disease intervention, and the valuable D.I.S. time its conduct will consume.

Standards

- A reinterview is considered only after an assessment establishes a high probability that it will produce disease intervention. Such assessment should include the following:
  - review of all pertinent records, reports and notes from the original interviewing/counseling session concerning factual omissions or unresolved patient problems;
  - the current status and results of sex partner referrals; and,
  - the identification of epidemiologic relationships, the existence of a potential source, and in particular, any suggestion of nondiscussed sex partners during the period the patient was infectious.

THE REINTERVIEW OF AN STD PATIENT

The reinterview of an STD patient is usually more pointed than the original interviewing/counseling session because it revolves around very specific problems related to the discussion and examination of sex partners; the core issue is the suspicion that the patient has been evasive about those he/she has exposed. The approach to this sensitive issue is critical to the success of the reinterview and merits the most extensive preparation possible. It must be timely to convey importance, pursued according to a carefully prepared agenda, and tactically planned to strongly encourage voluntary patient cooperation in the disease intervention process.

Standards

- To successfully achieve disease intervention, STD reinterviews are conducted in such a manner that each patient is:
  - seen reasonably soon after the original interviewing/counseling session (as soon as the last key item of readily accessible disease intervention information is available for analysis and planning, and certainly no longer than 10 days),
  - approached with a purpose and is tactfully led through a discussion planned on the basis of an analysis of available information and a judgment about its possible meaning; and,
  - positively, but assertively, confronted concerning any evasive behavior regarding the referral of sex partners or the treatment or followup of his/her recent infection.

THE CLUSTER INTERVIEW

Cluster interviewing is a process used with extreme selectivity. As with the reinterview, the need for this activity should diminish as improvements are made in the quality and impact of original interviewing/counseling sessions. The cluster interview is a controlled discussion with a person who receives a medical examination because of exposure or some other relationship to an STD case, but for whom physical examination and clinical tests show an apparent absence of disease. The purpose of the cluster interview is to gather information about previously unidentified sex partners of known cases and about individuals of concern (such as those with symptoms) who should be provided an STD examination. The objective of the cluster interview is to expedite disease intervention by expanding the base of information about the high-risk group. While cluster interviewing can be productive, it calls for a skilled procedure and requires committing D.I.S. time in exchange for a return that is difficult to estimate in advance. Thus, it should be used selectively, and should always be conducted with a precise purpose based on careful planning and analysis. As part of a special effort to address an outbreak situation, such as of early syphilis, PPNG, or CMRNG, clustering may have a more extensive role than under normal program circumstances.

Standards

- Persons who receive a cluster interview are:
  - selected on the basis of a reasoned judgment that they are likely to contribute information of disease intervention value for priority STD cases;
  - selected on the basis of a reasoned judgment that the index patient's exposure information is so questionable that to accept it without confirmation may result in the inappropriate provision or withholding of preventive treatment; and,
  - approached with an agenda developed from a thorough analysis of all available disease intervention information.
- To successfully achieve disease intervention or to obtain information which will advance it, STD cluster interviews are conducted such that each individual is:
  - given no information by the D.I.S. which would confirm that any specific sex partners or friends have disease, had disease, were exposed to disease, or received an examination for disease;
  - given logical reasons to conclude that it is in his/her personal interest to discuss his/her sex partners and the behavior of others to reduce the risk of disease in his/her sociosexual group; and,
  - provided easily understood information about the disease to which he/she has been exposed and logical, acceptable ways to avoid similar risk in the future.

INITIATION OF RECORDS

The basic work documents of the D.I.S. consist of the interviewing/counseling record and the Sexually Transmitted Disease Epidemiologic Report form (ERF). Some State and local STD programs utilize additional documents, such as reinterview and cluster interview records, Lot System forms, and visual documentation charts. Properly initiating work records is necessary to track the progress of case investigation activity, evaluate its outcome, and make the most efficient use of program resources.

Standards

- The program establishes and maintains a system which ensures that each work document is legible and initiated and processed in accordance with prescribed procedures.
- The program establishes and maintains a system to ensure that each initiated work document is completed within specified time requirements.

DOCUMENTATION OF WORK RECORDS

Effective disease intervention depends upon the legible, coherent, complete, current and timely documentation of work documents. In addition to proper initiation of each work record, D.I.S. are expected to record an ongoing documentation of their individual efforts. This is especially true of the ERF used in the followup of people at risk. Documentation is considered crucial because efficiency and desired results often depend upon knowing what has transpired to date with that patient. Firstline supervisors are responsible for periodic review of this information, both during the investigation and after it is closed.

Standards

- The program establishes and maintains a system to ensure that each disease intervention outreach activity work record is:
  - legibly, coherently, and accurately documented to permit the rapid reconstruction of all activities performed; and,
  - documented in timely fashion so that all open and active investigation records reflect the most current activity performed.

DIRECT FOLLOWUP ACTIVITIES

The followup and referral of individuals at identified risk for STD are integral parts of the disease intervention operations of an STD control program. Economic and staffing realities require that each program assign such followup activity according to rational priorities so that the most labor-intensive activity (field investigation and followup), is limited to those situations most likely to affect disease intervention outcomes and prevent complications. Most patients and their sex partners can receive the benefit of this direct service in some programs, while in many other programs, such serivces will be limited. When field investigations must be limited, all those in the following categories should be included for followup:

- women seen in hospital emergency rooms who have positive cultures for *N. gonorrhoeae* or *C. trachomatis* who have not been treated;
- other patients with positive cultures, especially resistant gonorrhea, who have not been treated;
- patients with high-titer STS for whom no history of treatment exists;
- women with a reactive prenatal STS; and
- sex partners of PPNG, PID, and infectious syphilis patients.

Since the techniques and procedures for following and refer such individuals are well developed and effective when executed correctly, the success of the process should be primarily dependent on timely execution.

Standards

- Program management clearly specifies acceptable levels of productivity and qualitative standards for direct followup activity and maintains accountability of program staff for meeting them.

INDIRECT FOLLOWUP ACTIVITIES

In many instances, an STD control program will be unable to utilize direct followup procedures. To effect disease intervention for these cases, the program should encourage others (such as providers who have initially seen the patient, or the patient himself/herself), to refer at-risk individuals for medical evaluation and treatment. Most STD programs have recognized the enormity of assuming the sole responsibility for ensuring that all patients receive adequate treatment, and have arranged for other health care providers—especially those performing gonorrhea screening tests—to make the initial effort. Only when these other providers are unsuccessful within an agreed upon time period will the STD program intervene in referral activities. More recently, STD programs have begun to encourage patients to refer some or all of their own sex partners for medical evaluation—again within strict time limits. Both referral activities are often successful and can be an extremely efficient alternative to committing health department resources. The State or local STD program, however, retains the responsibility for ensuring that patients referred in this manner receive prompt medical evaluation.

Standards

- The STD program has written policies indicating which patients may be indirectly referred and the time frames in which the referrals must be made.
- The STD program has a strictly monitored system to ensure prompt program intervention when indirect referral contracts are broken or do not succeed within the agreed time frames.

IX. STD OUTBREAK CONTROL INITIATIVE

A program area may experience such an increase of a particular STD that unusual disease intervention measures are necessary to reduce morbidity to a level that can be effectively managed. Historically, these initiatives have been triggered by a wide range of stimuli, from as few as one case in a small, previously disease-free community to the emergence of hundreds of cases that dramatically expanded the disease reservoir in a large metropolitan area. The necessity of each such initiative must be judged on the basis of individual program area criteria and circumstances. The initiatives are appropriate in many types of STD situations and have been used to combat a number of different STD, most often and most successfully with early syphilis and antibiotic resistant gonorrhea.

The diversion of resources and the restructuring of activities during an outbreak control initiative require the program manager to carefully consider the potential consequences, in addition to the benefits, of a successful initiative. A conscious decision to redirect resources, to sacrifice other STD control activities to implement the initiative, and to "reprogram" the D.I.S. staff, must take into account all the issues that may be affected.

The first phase of the initiative requires a formal epidemiologic assessment of the situation using sophisticated analysis of existing data.

This includes a review of both past and current trends of disease compared to disease intervention priorities and activities. It also involves confirming an outbreak and pinpointing its affected population and geographic foci. This information becomes the basis for planning.

The second phase of the initiative is its implementation. Preparing action plans and tracking systems are critical factors to its success. Preparation begins with an endorsement from local public health authorities and continues with an assessment of patient education activities, public service access to media should that be necessary (although any use of it is rare and usually media attention in meticuously avoided), and means to most effectively advise and involve the private medical community plus certain well informed and discreet people among affected groups (e.g., bathhouse managers, owners/bartenders of implicated night spots, etc.) who can assist with locating and identifying information. Preparation further involves a complete assessment of all cases related to the outbreak situation, as well as their associated investigations, pending diagnostic followups, and other STD control activities and obligations. In addition to currently assigned work, this assessment should include recently closed cases that have relevance. All assigned work should be analyzed, prepared with specific instructions concerning needed actions, and organized into a basic filing system complete with cross reference files (e.g., name to case number and file identification). The "Lot System" is a proven model for such a basic filing system. Manuals describing the Lot System used with either syphilis or antibiotic resistant gonorrhea are available through DSTD, CDC.

The existing resources must also be assessed for their capability of responding to the objectives of the initiative. For example, any STD clinics which will handle a sizeable number of D.I.S. referrals should be reviewed for compliance with the "Quality Assurance Guidelines for STD Clinics"; any deficiencies should be corrected to the maximum extent possible. In addition, whenever the preparation assessment discloses deficiencies in the performance of D.I.S. staff, it is critical that problems be corrected beforehand to avoid experiencing and intensifying the same problems during the outbreak control initiative. This correction process involves a needs assessment and the consideration of formal training, procedures for which are described in the "Quality Assurance Guidelines for Managing the Performance of Disease Intervention Specialists in STD Control." Likewise, the supervisory staff would have to be prepared to guide the D.I.S. in the implementation of the initiative. Finally, if the option exists, additional resources should be sought if justifiable.

Organization involves decisions about goals, action plans, timetables, and materials; most importantly, it involves personnel, their precise roles, and the lines of authority. Every person's responsibilities must be carefully defined and clearly communicated—no detail it is possible to anticipate should be left to chance or to somebody's unilateral determination. Attachment F includes one example of a description of responsibilities and a basic supply list for such an operation.

In organizing an outbreak control initiative, the greatest efficiency is maintained when normal case management responsibilities are divided into discrete components. However, the management team must insure that this process doesn't result in D.I.S. or supervisors doing task work without a clear perspective of the status of disease intervention in those cases with which they were involved. Everyone's continued participation in the decision-making process and sense of achievement is critical to maintaining staff morale. The delineation of roles should supplement the impact role of D.I.S., rather than isolate them from any sense of contributing to the overall process. In an outbreak control initiative then, critical case analysis and specific instruction preparation are centralized; reinterview and cluster interview assignments are made irrespective of who conducted the original interviewing/counseling session; field investigations are conducted without regard to the initiating D.I.S.; and field work is assigned according to the smallest possible divisions of the geographic area.

Lastly, the ongoing evaluation of the initiative is essential both to facilitate procedural, organizational, or logisti-

cal adjustments and to determine when to terminate activities based on predetermined goals or circumstances or factors of cost.

The DSTD, CDC has staff available to advise and assist program areas in carrying out all of these steps in an outbreak control initiative. In addition, resources available locally can assist. For example, while DSTD has trained epidemiologists who can assist in conducting the initial status assessment. State based EIS Officers or other staff epidemiologists, when available, may be able to provide this service just as well. DSTD also has staff with computer expertise who can help with data management and evaluation. Finally, DSTD has personnel expert in the preparation assessment and experienced in establishing the basic records system and management procedures needed for an initiative.

Standards

- The need for an outbreak control initiative is clearly defined by a formal epidemiologic analysis of the STD control status.
- The preparation for an outbreak control initiative includes a thorough assessment of current activity, the review of individual cases with detailed instructions, and the establishment of an efficient basic filing system.
- The preparation for an outbreak control initiative includes a review of the core STD clinic, a needs assessment of D.I.S. and any indicated arrangements for formal training as described in the "Quality Assurance Guidelines for Managing the Performance of Disease Intervention Specialists in STD Control."
- The organization of an outbreak control initiative includes goals, action plans, timetables, and materials, plus the precise definition and clear communication of individual responsibilities to everyone involved.
- Each outbreak control initiative includes an evaluational component which is sufficiently precise to detect problems, permit immediate adjustments, and accurately signal when to terminate activities based on predetermined goals or changes in the situation and/or factors of cost.
- Any program manager without prior experience in planning and implementing an outbreak control initiative actively seeks support and assistance from DSTD, CDC.

X. ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)

HEALTH PROMOTION/RISK REDUCTION

Acquired immunodeficiency syndrome (AIDS) is a condition which will have increasing impact on STD control activities for the foreseeable future. By providing other STD services to individuals who possibly have been exposed to the human T-lymphotropic virus, type III (HTLV-III), STD control programs are in a unique position to influence behaviors that may limit the spread of this STD as well. Persons in risk groups particularly vulnerable to HTLV-III infection and AIDS (e.g., gay men, prostitutes, IV drug users, and their sex partners) who receive various STD program services should receive counseling by STD staff. This counseling should cover the AIDS problem, the risks inherent in the person's particular sociosexual lifestyle, and behavioral options that may reduce the risk of acquiring or transmitting the virus. This is a particularly appropriate topic for D.I.S. staff during interviewing/counseling session segments which cover the person's specific recent sexual activities and practices. However, STD clinicians also can be an important source of information and counseling because they are quite likely to receive specific patient inquiries during the STD examination process.

Standards

- Persons receiving various STD clinical and disease intervention outreach services who possibly have been exposed to the HTLV-III virus are counseled regarding their risk of infection with the virus and behavioral options that may reduce this risk.
- All STD program staff members involved in AIDS/HTLV-III infection health promotion and risk reduction counseling activities are periodically observed by appropriate supervisors to ensure that accurate and consistent messages are being delivered in a sensitive manner and that all questions are being answered accurately.

HTLV-III VOLUNTARY ANTIBODY TESTING AND COUNSELING

A number of project areas have determined that STD program staff will assume certain responsibilities for HTLV-III antibody testing and counseling. Wherever this decision has been made, it is essential that each component be carefully planned and managed to ensure that all services are sensitively delivered to fully informed volunteers and are of the highest quality possible. This includes procedures to ensure strict confidentiality, a carefully articulated message about the appropriateness and availability of testing services, a counseling component through which all patients receive sensitively delivered and consistent information pertinent to their particular sociosexual situation, and networks of professionals to whom patients can be referred for competent medical and mental health evaluation.

Standards

- STD program HTLV-III antibody testing services are structured to ensure maximum confidentiality for all persons voluntarily tested and counseled.
- All STD program staff conducting pretest and posttest counseling activities related to HTLV-III antibody testing have their performance periodically observed by a firstline supervisor to ensure that the information conveyed is consistent, accurate, and delivered in the most sensitive manner possible.
- STD program management ensures that a network of medical and mental health professionals is established to permit counseling staff to smoothly effect referrals and to minimize the problems which patients encounter in receiving the necessary services.

XI. CHILD ABUSE

Any STD infection in a child (less than 13 years of age) should be considered as an indication of possible sexual abuse until proven otherwise. Such cases should be promptly reported to the appropriate authorities for follow-up, since these children are best managed by professionals experienced in handling their physical and psychological needs.

Interviewing/counseling of infected children should be conducted by, or in cooperation with protective services staff or such children should be turned over to them entirely.

Standards

- The program will establish and implement a formal written policy for handling suspected child abuse. This policy should include:
  - procedure for reporting of suspected cases,
  - referral procedure for children, and
  - procedure for interviewing/counseling and followup or total referral to staff responsible for child abuse cases.

XII. LEGAL AUTHORITIES FOR STD CONTROL

Congress has specifically authorized and appropriated Federal funds for projects and programs to prevent and control sexually transmitted diseases in section 318 of the Public Health Service Act, 42 U.S.C. section 247C. No Federal laws *mandate* domestic STD control activities. All legal authorities for domestic STD control program *operations* emanate from statutes or regulations enacted by States or their political subdivisions. Although laws vary widely, certain authorities are common to most States and are necessary for STD programs to operate effectively. The first of these authorities is enabling legislation which allows program operations and generally includes:

1. Definitions of the diseases to be controlled;
2. Rulemaking authority, or the ability to establish health regulations that have the effect of law;
3. Health officer responsibility to take reasonable and appropriate control measures;
4. Health department authority to investigate disease occurrence and outbreaks;
5. Quarantine and isolation of persons refusing needed examination and treatment;
6. Diagnostic and treatment services to be provided;
7. Provision for minors to authorize their own STD examination and treatment;
8. STD education established as part of the public school curriculum;
9. Authorization for field staff to perform venipuncture; and,
10. The requirement and/or guarantee of confidentiality of STD patient service and program disease intervention outreach records.

The second general category of STD legislative authority contains case detection and disease surveillance statutes or regulations which allow for disease intervention activities. They generally include four areas of concern:

1. Morbidity reporting—to include patient identifying and demographic information;
2. Reactor reporting—by clinical laboratories to promptly report positive test results;
3. Premarital testing—several States have recently rescinded this law; and,
4. Testing of high-risk groups, such as persons arrested for prostitution, before their release.

The third general category contains medical/public health practice authorities, or those which address appropriate procedures necessary to ensure optimal patient care and preventive medicine. They generally include the following:

1. Prenatal serologic testing;
2. Ophthalmia neonatorum prophylaxis requirement by persons attendant at childbirth;
3. Prophylactic methods, principally condoms, which may be freely advertised and sold in localities other than through licensed pharmacies; and,
4. Restriction of false advertising of cures, curative agents, or of curative facilities for STD.

As time passes, the wording and circumstances surrounding STD legislation change, requiring a revision of existing law. When this occurs, the program manager normally takes the initiative and works in concert with the State health department's legal counsel to bring about the needed revisions.

Standards

- Each State has a complete set of legal authorities (statute or regulation with statutory authority), which includes the following:
  - definitions of diseases to be controlled, including morbidity reporting by name, address, disease, sex, age, race and source of report;
  - confidentiality of STD records to the maximum extent legally possible including exemption from subpoena (samples of statutory and common law case precedents from selected states are available from the Division of Sexually Transmitted Diseases, Centers for Disease Control);
  - prenatal serologic testing to include at least one serologic test during both the first and third trimester of pregnancy;
  - ophthalmia neonatorum prophylaxis;
  - permission for minors to authorize their own STD examinations and treatment without parental consent and holding this and related information absolutely confidential;
  - venipuncture by field staff;
  - laboratory reporting of positive tests to include time frames, name of physician; patient's name, age, race, sex, tests performed and test results; and,
  - STD education in public schools to ensure STD information is taught uniformly as part of the public school curriculum.
- Each program has a system to ensure that such laws are reviewed and revised, if necessary.

Appendix A

Prototype

Process Performance Standards for Disease Intervention Specialists in STD Control

I. PHILOSOPHY AND APPROACH

A. The "success" or "failure" of any Disease Intervention Specialist (D.I.S.) effort will be judged as much by the quality of the process performance delivered as by the disease intervention results produced.

B. The overall pursuit of any disease intervention request originating in another State or health jurisdiction, be it an investigation, interviewing/counseling session, reinterview, or information check, will be accorded *no less a priority* than if the activity were to originate within the area.

C. All interviewing/counseling and investigative activities will be conducted in such a way as to safeguard the identities of infected individuals and to conceal the identities of others suspected of having disease.

D. A D.I.S. will take all reasonable precautions to ensure all disease intervention records and medical documents, as well as their contents, are revealed only to persons who have legally authorized access to them.

II. INTERVIEWING/COUNSELING ACTIVITIES

A. **Preinterview Preparation**

Before any original interviewing/counseling session, the D.I.S. undertakes a thorough analysis of:

- available medical records;
- available historical information pertinent to the current infection;
- interviewing/counseling and investigative records for evidence of relationships to other known cases; and,
- information from other D.I.S. staff.

B. **The Interviewing/Counseling Session**

1. To achieve maximum disease intervention, the D.I.S. conducts STD interviewing/counseling sessions without delay after the case comes to program attention.
2. In conducting each interviewing/counseling session a D.I.S. competently:
   a. Demonstrates professionalism (self-confidence, competence, and objectivity);
   b. Emphasizes confidentiality and the discretion with which the program operates;
   c. Conveys a sense of urgency and mission;
   d. Establishes rapport and demonstrates concern for the patient;
   e. Listens and assesses the patient's needs correctly;
   f. Uses open-ended questions;
   g. Communicates at the patient's level;
   h. Delivers disease intervention behavioral messages appropriate to each patient's situation;
   i. Emphasizes sex partner referral and assumes ultimate responsibility for the outcome of these efforts;
   j. Recognizes problem indicators and appropriately responds or motivates;
   k. Confronts resistance or evasion firmly, when necessary, while maintaining professional composure.
   l. Persists tactfully to ensure all at risk sex partners are identified.
   m. Pursues detailed information to identify and locate sex partners (e.g., routinely seeks to obtain *at least two items* of locating information, address and telephone number counting as one item).
   n. Establishes *specific* (i.e., time and place) contracts and "coaches" any patients who undertake sex partner referrals.

C. Specific interviewing/counseling situations will be managed as follows:

1. When a patient alleges to have sex with marginally identifiable or locatable people ("Marginals," i.e., pickups, prostitutes, bathhouse patrons, etc.), a D.I.S. will:
   a. Motivate the patient to discuss people they know; and,
   b. Challenge the patient to provide the most exhaustively complete locating and identifying information possible for the marginals, including:
      1) Routine descriptive items, i.e., age, sex, race, marital status, height, weight, hair color, and complexion;
      2) Unique descriptive characteristics, i.e., glasses, jewelry, facial hair, scars, impairments, etc;
      3) The individual's "most outstanding physical characteristic;"
      4) Where the sex partner was first encountered;
      5) Known others who were present and/or who may have locating information;
      6) Where sex took place;
      7) Map of the street or area where the individual lives, works, or hangs out; and
      8) Arrangements for future liaison.
2. All male patients who allege or recount having sex only with females will be asked about sex with other men; likewise, male patients who name only male sex partners will be asked about sex with women.
3. Whenever appropriate, patients will be asked about their address book and their willingness to share it to expedite the referral of sex partners.
4. For all designated priority original interviewing/counseling sessions conducted in a clinic, the D.I.S. will confer with the firstline supervisor or a coworker to review all results and commitments before releasing the patient.
5. Selective reinterviews or cluster interviews are conducted in person and based on:
   a. A clear disease intervention need whose priority over other STD intervention opportunities can be fully justified to the firstline supervisor;
   b. A specific purpose;
   c. A predetermined plan;
   d. Timely execution; and
   e. Competent performance of the skills required to achieve the purpose.

D. **Postinterviewing/Counseling Session Analysis and Decisionmaking**

After the interviewing/counseling session has concluded, a D.I.S. will:

1. Search for information on sex partners to determine any prior medical or disease intervention records relevant to the present case;
2. Review standard investigative resources to confirm locating information on all sex partners;
3. Analyze the disease intervention information on identified sex partners and accurately determine probable relationships, possible factual omissions, set priorities for field investigations, and potential avenues to pursue future disease intervention.
4. Determine the need for reinterviews and/or cluster interviews or decide, with consultation from the firstline supervisor, about whether to discontinue further activities.

E. **Reinterview Analysis and Preparation**

A D.I.S. considers a reinterview only after conducting an assessment that establishes a high probability that it will produce disease intervention. Such assessment will include the following:

1. Review of all pertinent records, reports and notes from the original interviewing/counseling session concerning factual omissions or unresolved patient problems;
2. The current status and results of sex partner referrals; and,
3. The identification of epidemiologic relationships, the existence of a potential source, and in particular, any suggestion of nondiscussed sex partners during the period the patient was infectious.

F. **The Reinterview**

A D.I.S. conducts a reinterview in such a manner that each patient is:

1. Seen reasonably soon after the original interviewing/counseling session (as soon as the last key item of readily accessible disease intervention information is available for analysis and planning, and certainly no longer than 10 days),

2. Approached with a purpose and is tactfully led through a discussion planned on the basis of an analysis of available information and a judgment about its possible meaning; and,
3. Positively, but assertively, confronted concerning any evasive behavior regarding the referral of sex partners or the treatment or followup of his/her recent infection.

G. **The Cluster Interview**

1. A D.I.S. approaches and conducts cluster interviews such that the persons interviewed are:
   a. Selected on the basis of a reasoned judgment that they are likely to contribute information of disease intervention value for priority STD cases;
   b. Selected on the basis of a reasoned judgment that the index patient's exposure information is so questionable that to accept it without confirmation may result in the inappropriate provision or withholding of preventive treatment; and,
   c. approached with an agenda developed from a thorough analysis of all available disease intervention information.
2. A D.I.S. conducts each STD cluster interviews are conducted such that each interviewee is:
   a. Given no information by the D.I.S. which would confirm that any specific sex partners or friends have disease, had disease, wereexposed to disease, or received an examination for disease;
   b. Given logical reasons to conclude that it is in his/her personal interest to discuss his/her sex partners and the behavior of others to reduce the risk of disease in his/her sociosexual group; and,
   c. Provided easily understood information about the disease to which he/she has been exposed and logical, acceptable ways to avoid similar risk in the future.

III. INVESTIGATION ACTIVITIES

A. Observing program guidelines, a D.I.S. will routinely make appropriate determinations of high and low priority investigations and organize field activity accordingly.

B. Within 24 hours of assignment, a D.I.S. will, at a minimum, verify the locating information on any sex partner, priority cluster, or priority diagnostic followup from public sources.

C. Within 24 hours of assignment of priority diagnostic followup of private physician patients, a D.I.S. will consult with the private physician to obtain information regarding the diagnosis and treatment, symptomatology, and permission for interviewing/counseling and sex partner followup.

D. All standard locating resources (e.g., telephone book, cross directory, closed ERF's, clinic medical records, utility companies, public assistance files, driver's license bureau, telephone company security, etc.) will be consulted whenever and to whatever extent they are appropriate to any particular investigation.

E. Intervals between action steps on any priority investigation shall not exceed one working day, except under extraordinary circumstances that can be justified to the firstline supervisor.

F. Any D.I.S. referral, particularly of sex partners and other priority persons, will be for no longer than the next clinic day. This will be standard whether the referral is made in person or by a referral card. The D.I.S. will reinitate followup on all patients who failed their appointments within 1 working day.

G. Mailed letters are not a substitute for field or telephone referral and will be utilized only in conjunction with such referrals or after such referrals have proven unsuccessful—*and* only with supervisory permission.

H. A referral card will be left for an investigated person only after a reasonably exhaustive investigation has failed to bring about personal or telephonic contact.

I. Without prior authorization from the firstline supervisor, referral methods which have failed once will not be repeated (e.g., calling the same number at the same approximate time of day, leaving referral cards at the same address, etc.).

J. When informing sex partners of their risk situation, a D.I.S. will avoid implying or stating that the individual is, in fact, infected with disease.

K. Any persons under investigation, particularly those designated as priority, who appear to be unlocatable or who refuse examination, will be discussed with the firstline supervisor as soon as that status is determined.

V. Records

A. Initiation

1. A D.I.S. takes responsibility to ensure that each work document initiated is legible and is processed in accordance with the procedures prescribed for that particular record.
2. A D.I.S. satisfactorily completes and appropriately files or prosesses each interviewing/ counseling record within 1 working day of when the session occurred and does the same with ERFS initiated on sex partners and clusters identified.

B. Documentation

1. A D.I.S. will document each investigative step immediately after the activity has occurred and will reflect the date, time, and nature of that activity. This dated activity will be recorded on the reverse side of the field copy of the ERF and will be *legible and interpretable.*
2. A D.I.S. takes responsibility to ensure that each disease intervention outreach activity work record is so legibly, coherently, and accurately documented that it permits the rapid reconstruction of all activities performed and a timely assessment of the most current activity performed on all open and active investigations.

Appendix B

Gonorrhea Screening: A Commentary on Operational Quality Control

The attached prototype operational quality control checklist can be used as a guide by those program employees assigned to visit facilities that participate in the gonorrhea screening program. Section I of the form should be used to organize information prior to the visit; Section II should be used to record observations and to summarize recommendations.

The tone of such Operational Quality Control visits as well as the content can make a significant contribution to overall effectiveness. If a sexually transmitted disease control program employee visits a participating facility simply to ask a series of questions of a worker at that facility, the impact of the visit will be greatly limited. The answers called for on the attached checklist are intended to be *direct observations* in as many instances as possible and not simply the answers to questions directed toward one or two persons. For example, asking a worker the temperature of the incubator can produce very little insight into the problems which can be encountered in screening for *N. gonorrhoeae* at that facility. The person performing the quality control visit must function as a problem identifier and create liaisons between the program and its variety of services and the health care facility.

Operational Quality Control is a high program priority. Yet, such visits and the resultant accumulation of information represent but one element of the total quality control process. This process includes at least three other elements.

1. **An efficient system to distribute culture media to participating facilities and to supply needed items of equipment such as incubators.** This program element focuses on keeping facilities provisioned with adequate amounts of fresh media, and monitoring the number of cultures performed versus the number of plates distributed. The "loan" of an incubator to a screening site is often a necessary supplement to other program input and it is impractical for managers to avoid this sort of purchase when the return in terms of additional infected persons identified can be most significant.
2. **Ongoing monitoring of results obtained by each participating facility.** Tallies on a weekly or biweekly basis should include, in addition to negative and positive findings, the number of specimens judged to be unsatisfactory at time of examination in the laboratory. Careful monitoring of such data can lead to programmatic action including additional problem solving visits.
3. **Laboratory measures.** The last aspect of operational quality control involves those items which are laboratory based, e.g., the checktesting of media, quality control of reagents, matching results of Gram stained smears and urethral cultures in men, etc. Each of these items can be the subject of lengthy discussion, and CDC has already distributed recommendations concerning many of them.

As a complement to media testing in the laboratory, the value of the simple system of comparing Gram stain and culture results cannot be overemphasized. All sexually transmitted disease clinics are encouraged to obtain specimens from the urethra of men with positive Gram stained smears and to inoculate these specimens on the type of culture media being used by the program. This approach need not involve hundreds of specimens per month. It is our suggestion that an initial sample of 10 to 20 such dual specimens be taken at a sexually transmitted disease clinic for each lot of culture media. The correlation between these results should be 95% or better. Any result that is significantly less than 95% warrants in-depth evaluation.

To sum up this discussion of operational quality control, we do not see true quality control in gonorrhea screening efforts as being a one-faceted effort. Those issues involving in-laboratory procedure, field visits to the participating facilities, monitoring of test results and distribution of materials are of equal importance at least in the sense that, for a program to be successful, all facets must be performed well. We would ask that you review this commentary, the attached checklist for quality control visits, and any other pertinent documents on in-laboratory quality control and then apply such measures to the ongoing screening program in your area.

GONORRHEA SCREENING

Section I: Participating Facility Summary

Participating Facility _____

Type of Facility _____

Address _____

Phone Number _____

Contact Person _____

Title _____

A. **Screening History**

Average Monthly Volume of Tests* _____

Percent Positive _____

Percent Overgrown _____

Percent Unsatisfactory _____

*Significant recent deviations should be noted separately.

B. **Current Status of Media Supply**

_____Units shipped

- ☐ Weekly
- ☐ Bi-weekly
- ☐ Monthly
- ☐ Other

C. **Type of Media Used**

- ☐ Modified Thayer-Martin
- ☐ Transgrow
- ☐ Other _____

D. **Packaging (CO_2 Enrichment)**

- ☐ Candle Jars — Type: _____
- ☐ JEMBEC
- ☐ Transgrow
- ☐ Other _____

E. **Transportation System**

☐ Courier _____

☐ U.S. Postal System

☐ Facility Employee to Laboratory

☐ Other _____

F. **Average Time Between Submission of Specimen and Return of Results**

_____ Days Maximum time _____ Days

Section II: Checklist for Each Quality Control Visit

Issue	Desired Performance	Observations
1. **Media Storage**		
A. Refrigerator used	Yes	☐ YES ☐ NO
B. Thermometer installed/ acceptable range	Yes 2 - 8 C	☐ YES ☐ NO ____°C
C. Media stored in sleeves	Yes	☐ YES ☐ NO
D. Media stored "agar side up" and away from freezer unit	Yes	☐ YES ☐ NO
E. Outdated media noted	None	☐ YES ☐ NO
F. Media brought to room temperature	Yes—removed from refrigerator 2 hours (variable) prior to inoculation	☐ YES ☐ NO
G. Other		
2. **Obtaining the Specimen/Inoculation**		
A. Endocervical specimens obtained	Cervix seen, specimen obtained from the endocervical canal, not simply from surface of cervix or vaginal vault	☐ Yes ☐ No
B. Sterile swabs used	Yes	☐ YES ☐ NO
C. Routine anal canal cultures for screening purposes	No	☐ YES ☐ NO

D. Anal canal cultures obtained as part of test-of-cure procedure in women	Yes	☐ YES ☐ NO
E. For male patients (if applicable)—urethral specimens obtained with "Calgi" swab or wire loop	Yes—not cotton tipped applicator	☐ YES ☐ NO ☐ Calgi swab ☐ Wire loop
F. Plate inoculated by rolling swab across surface ("Z" pattern or comparable)	Yes	☐ YES ☐ NO
G. Other		

3. **Specimen Handling after Inoculation**

A. Cross Streaking	Yes—with sterile wire loop	☐ YES ☐ NO ☐ Onsite ☐ In laboratory
B. Specimens placed under CO_2 tension	Yes—within 10-15 minutes	☐ YES ☐ NO ☐ Within____minutes
C. If candle jar is used, adequate space between top of plates and lid	Yes—3 inches	☐ YES ☐ NO
D. If candle jar is used, plates are stacked agar side up	Yes	☐ YES ☐ NO
E. Specimens incubated onsite	Yes—within 2 hours	☐ YES ☐ NO
F. Incubator has thermometer	Yes	☐ YES ☐ NO
G. Incubator temperature observed	35 °C	☐ YES ☐ NO ____°C
H. Temperature chart affixed to incubator and reading noted	Yes—daily	☐ YES ☐ NO
I. Other		

4. **Transportation of Inoculated Specimens**

A. Method

☐ Courier
☐ Mail
☐ Other _____

B. Schedule of Sessions*

Time of transportation of specimens**

1.
2.
3.
4.
5.
6.
7.

*Enter day and time(s) of medical care sessions.

**Enter either time of courier pickup or the time the specimen is transported to a postal station. *Specimens once placed under incubation should remain in such a condition for 18-24 hours.*

C. Other

5. **System(s) to Ensure Treatment**

A. Notification of Patients of Positive Tests

☐ Patients are given return appointments within ____ days.

☐ Patients are asked to call back for results within ____ days.

☐ Patients are notified by facility if positive findings.

Method _____

Other _____

B. Treatment—Facility treats its infected patients

☐ YES ☐ NO

If facility does not treat, state reason(s)

_____

_____

_____

C. If facility treats, most used regimen for nonallergic (PCN) patients

☐ APPG + Probenecid
☐ Ampicillin
☐ Combination or Other

If facility treats, most used regimen for allergic (PCN) patients and Rx failures

☐ Tetracycline HCl
☐ Spectinomycin
☐ Combination or Other

D. Followup system (if patient misses appointment for treatment)

☐ Health Department
☐ Phone call by facility

☐ Letter by facility
☐ Other _____

6. **Other Considerations**

A. Are patients routinely scheduled for test-of-cure visits? ☐ YES ☐ NO

If yes, state interval between treatment and scheduled visit.
____ days

B. Are patients routinely scheduled for "rescreening" visits? ☐ YES ☐ NO

If yes, state interval between treatment and scheduled visit.
____ days

C. Does facility routinely counsel infected patients? ☐ YES ☐ NO

If yes, describe methods used, personnel involved, etc.

_____

_____

_____

CORRECTIVE ACTION

_____

_____

_____

_____

_____

_____

Appendix C

General STD Intervention Outcome Expectations

A. Interviewing/Counseling Outcome

- Number of interviewing/counseling sessions, reinterviews and cluster interviews assigned.
- Number of interviewing/counseling sessions, reinterviews and cluster interviews completed and time factors for each from date of assignment:[1]

Excellent:	Public—	95 percent within 1 day, 98 percent within 5 days
	Private—	85 percent within 5 days
Good:	Public—	85 percent within 1 day, 90 percent within 5 days
	Private—	75 percent within 5 days
Average:	Public—	75 percent within 1 day, 85 percent within 5 days
	Private—	70 percent within 5 days
Minimal:	Public—	75 percent within 1 day, 85 percent within 5 days
	Private—	60 percent within 5 days, 70 percent within 10 days.

- Number of sex partners initiated:

Excellent:	Early syphilis (Primary, Secondary, Early Latent < 1 Year)	4.00 or higher
	Resistant gonorrhea	2.00 or higher
	Other	1.50 or higher
Above Avg:	Early syphilis	3.00
	Resistant Gonorrhea	1.50
	Other	1.25
Average:	Early syphilis	2.50
	Resistant Gonorrhea	1.25
	Other	1.00
Minimal:	Early syphilis	2.00
	Resistant Gonorrhea	1.00
	Other	.90

- Number of people newly treated around each case (See Appendix E for explanation of treatment index):

Excellent:	Early syphilis	3.00
	Resistant Gonorrhea	1.75
	Other	1.25
Above Avg:	Early syphilis	2.50
	Resistant Gonorrhea	1.25
	Other	1.00
Average:	Early syphilis	2.00
	Resistant Gonorrhea	1.00
	Other	.80
Minimal:	Early syphilis	1.00
	Resistant Gonorrhea	.90
	Other	.70

[1] Date of Assignment—The *first* date work is given to a D.I.S. to be completed.

- Number of cases with disease intervention (See Appendix E for explanation of disease intervention index):

Excellent:	All interviews	.90
Above Avg:	All interviews	.80
Average:	All interviews	.70
Minimal:	All interviews	.60

- Weighted case prevention results (See Appendix E for explanation of weighted case prevention index):

Excellent:	Early syphilis	1.00
	Resistant Gonorrhea	.90
	Other	.90
Above Avg:	Early syphilis	.90
	Resistant Gonorrhea	.75
	Other	.65
Average:	Early syphilis	.75
	Resistant Gonorrhea	.65
	Other	.60
Minimal:	Early syphilis	.50
	Resistant Gonorrhea	.50
	Other	.50

B. Investigative Outcome

- Number of investigations assigned.

- Number of investigations completed successfully and time factors for each from date of assignment:

Excellent:	High priority (as defined by the program)—85 percent in 3 calendar days; 90 percent in 7 calander days.
	Low priority—70 percent in 7 calendar days; 85 percent in 10 calendar days.
Above Avg:	High priority—70 percent in 3 calendar days; 85 percent in 7 calendar days.
	Low priority—60 percent in 7 calendar days; 80 percent in 10 calendar days.
Average:	High priority—65 percent in 3 calendar days; 80 percent in 7 calendar days.
	Low priority—50 percent in 7 calendar days; 75 percent in 10 calendar days.
Minimal:	High priority—60 percent in 3 calendar days; 75 percent in 7 calendar days.
	Low priority—45 percent in 7 calendar days; 70 percent in 10 calendar days.

C. Surveillance

1. Gonorrhea screening

Positivity rate—Since gonorrhea prevalence is highly variable from one area to another, each program must base the quality of its surveillance activity on how completely individual providers are evaluated for screening yield. Positivity rates are confirmed through operational quality control. No quantitative measure is valid for this activity since the rate will depend on the extent of disease in the community.

Number of patients identified through screening who are treated and time factors for each from date of test:

Excellent: 85 percent in 7 calander days; 97 percent in 14 days.
Good: 80 percent in 7 calander days; 95 percent in 14 days.
Average: 75 percent in 7 calander days; 93 percent in 14 days.
Minimal: 70 percent in 7 calander days; 90 percent in 14 days.

2. Other Gonorrhea Surveillance

Percent of original positive cultures that are tested in public health laboratories for β-lactamase production:

Excellent: 100 percent
Above Avg: 95 percent
Average: 90 percent
Minimal: 85 percent

Percent of original positive female patients seen in public clinics returned for test of cure:

Excellent: 70 percent
Above Avg: 60 percent
Average: 55 percent
Minimal: 50 percent

3. Reactor Surveillance

Number and volume of reactors by individual laboratory.

Time factors for reporting of reactive tests:

Excellent: 90 percent within time specified in State regulation
Above Avg: 85 percent within time specified in State regulation
Average: 80 percent within time specified in State regulation
Minimal: 75 percent within time specified in State regulation

Appendix D

Sample Reactor Grid*

	WR	1:1+1:2	1:4	> 1:8	Qual or FTA only	D.F. Pos.
0-1	1	1	1	1	1	1
2-11	1	1	1	1	1	1
12-30	4	2	2	3	2	3
31-39	4	4	2	3	2	3
40-49	4	4	2	3	2	3
50-64	4	4	4	2	4	3
> 64	4	4	4	4	4	3

1 High priority—refer to special team—record search, if no record, initiate field investigation

2 Low priority—record search, review chart and close if possible, if no chart or record, send motivational letter

3 High priority—refer to field after negative record search

4 Administrative closure—no record search and no followup

*Must be tailored to local program needs

Appendix E

Selected Indices for STD Output Evaluation

CATEGORY

CALCULATION

Contact Index:

Number of sexual partners named on original and all reinterviews
(Number of cases interviewed/counseled)

Treatment Index:

$$\frac{\#OX + \#01 + \#02 \text{ dispositions}^*}{(\#\text{ of cases interviewed/counseled})}$$

Disease Intervention Index:

$$\frac{\#\text{ of cases with at least one sex partner with disposition 01, 02, or OX}}{\#\text{ of cases interviewed/counseled}}$$

Weighted Disease Intervention Index:

$$\frac{\text{Sum of weighted 01, 02 + OX dispositions}}{\#\text{ of cases interviewed/counseled}}$$

Weights for this index are:

Primary syphilis	0.9
Secondary syphilis	0.5
Early latent *A* 1 yr.	0.2
Other syphilis	0.05
Cluster to primary,Sec	0.65
Other cluster	0.08
Gonorrhea	0.7

Preventive treatment

Last exposure to syphilis
- 0-20 days -0.33
- 22-30 days-0.3
- 31-59 days-0.17
- 60-90 days-0.07
- *F* 90 days-0.00

Last exposure to gonorrhea
- 0-10 days-0.5
- 11-30 days-0.3
- 31-60 days-0.1
- 61-90 days-0.05
- *F* 90 days-0.00

Case Prevention Index:

Number of preventatively treated sexual partners exposed within 30 days (syphilis) 10 days (gonorrhea)

(Number of cases Interviewed/Counseled)

*According to disposition codes contai .. on CDC 73.2936, Sexually Transmitted Disease Epidemiologic Report form

Appendix F

STD Outbreak Control Initiative

Rationale and Responsibilities

Rationale

1. To provide *uniformity and thoroughness* to disease intervention analysis that is difficult if not impossible under normal circumstances.

2. To *free Disease Intervention Specialists* (D.I.S.) to carry out disease intervention activities with extraordinary speed and effectiveness.

3. In sum, *to get ahead of the spread of disease* by identifying as many epidemiologically involved people as possible and treating or preventively treating most of them.

Responsibilities

The Operations Coordinator

1. Maintain the basic filing system and all cross reference files so they are current, understandable, and immediately accessible.

2. Continually analyze the results of all current disease intervention activities and update appropriate records based on an immediate review of incoming information resulting from disease intervention activities.

3. Prepare instructions for the original interviewing/counseling session with individuals epidemiologically related to known cases.

4. Make decisions on the appropriateness of reinterviewing any cases and of cluster interviewing specific individuals involved in the outbreak.

5. Prepare instructions for the reinterview and cluster interview of any persons for whom these activities are deemed necessary.

6. Issue work assignments to the Field Coordinators for immediate reassignment to D.I.S.

7. Conduct the ongoing analysis of activities and impact and make or direct adjustments as indicated.

Field Coordinators

1. Make assignments of work to the D.I.S. staff.

2. Maintain tickler files of all assigned work.

3. Review instructions with D.I.S. prior to the execution of reinterviews, cluster interviews, and original interviewing/counseling sessions with persons brought to treatment or otherwise determined to be epidemiologically related to cases in the outbreak.

4. Review preliminary results with D.I.S. staff conducting original interviewing/counseling sessions.

5. Periodically review D.I.S. workloads, no less often than once each day.

6. After consultation with the Operations Coordinator and affected D.I.S. staff members, conduct reinterviews on problem and/or critical cases.

7. Stand prepared to conduct original interviewing/counseling sessions, necessary reinterviews, or selected cluster interviews when staff overloads occur.

8. Be prepared to cover night clinics working in any indicated capacity.

9. Be prepared to conduct evening investigations with staff, if that is the only time individuals can be located.

Disease Intervention Specialists

1. Perform all assigned activities in the most professional manner possible by applying all acquired skills to the maximum extent in every situation.

2. Seek immediate assistance from a Field Coordinator in any instance where required skills are lacking or in need of strengthening.

3. Initiate all paperwork as promptly as possible according to accepted standards of completeness and legibility and turn it in immediately to the Operations Coordinator.

4. Thoroughly and legibly document all field investigation activities on the reverse of the ERF, including worker identification and date, and time of day, if appropriate.

5. Check with a Field Coordinator after each original interviewing/counseling session prior to releasing the patient.

6. Review instructions with a Field Coordinator, the Operations Coordinator, the file, or all three prior to executing.

7. Review all instructions keeping in mind they represent suggestions and not mandates.

8. Surrender ERF's on all persons appointed in.

9. Cooperatively review all pending work with a Field Coordinator at any point a request is made.

Supply and Material Checklist

(Specify Quantities as Appropriate)

- Typewriter
- Typing Paper
- Copying Machine
- Stapler
- Staples
- Staple Remover
- Paper Clips
- File Box to Hold ERF's
- Standard Size Manila File Folders
- Files Boxes to Hold Manila File Folders
- Mending Tape
- 4-Part ERF's
- Buff Copy ERF's
- Multicopy Interviewing/Counseling Records
- Buff Copy Interviewing/Counseling Records
- Reinterview Records
- Cluster Interview Records
- Case Analysis Charts
- Case Analysis Rulers
- Manila File Folders
- 5" x 8" Index Cards
- 5" x 8" White Pads
- Venipuncture Equipment for the Field
- RPR Rotator, Centrifuge, and Antigen
- Darkfield Microscope and Supplies
- Brightfield Microscope and Supplies for Conducting Gram Stain
- Antibiotics

Appendix G

Federal References for STD Program Managers

Introduction

STD program managers and members of their staffs occasionally encounter problems with or receive inquiries concerning Federal laws and institutions. To assist in managing such situations, this appendix provides some references that explain various agreements, policy positions, interpretations, and regulations.

- **U.S. Postal Service Regulations Regarding Change of Address Information**

The U.S. Postal Service for years has made specific provision that State and local health department personnel can obtain address information for persons involved in communicable disease investigations. The most current governing reference is as follows:

> POSTAL BULLETIN 21459 5-24-84, page 3
> B. Fee Policy
> Effective January 1, 1985, the Postal Service will revoke its current policy of waiving the fee for *all* Government agency requests for address information and begin charging most Government agencies the regular $1 fee. Specifically, after January 1, 1985, the fee will be waived only for requests from:
> ... 4. Federal, State, and local *public health officials* for the purpose of locating persons who are infected with or have been exposed to contagious diseases.

Local postal officials very often are cooperative with properly identified health department personnel who make requests in person. If time permits, many Postal Service employees will research address change information on the spot without excessive inquiry about whether the individual is infected with or exposed to a disease. In some Postal Service facilities, time will not permit an immediate search or policy mandates that all such inquiries must be made in writing. The Postal Service requires a standard format be used in making such written requests. POSTAL BULLETIN 21459 includes a recommended format which is reproduced, with appropriate modifications, as Exhibit 1 at the end of this Appendix.

- **Reporting and Other Cooperation by the Uniformed Services**

Officers and personnel of the Uniformed Services of the United States are under explicit instructions to cooperate with State and local STD control programs. This cooperation consists of submitting laboratory and morbidity reports as provided in law, ordinance, or health department regulation, and of working with State/local STD programs in pursuing disease intervention outreach objectives.

The authority mandating this cooperation begins with the Seven Point Agreement of 1967, the most current version of a pact which has antecedents dating from the early 1950's. The agreement appears as Exhibit 2 toward the end of this Appendix. Note that Article 1 is unambiguous about reporting. Over the years, the specifics of this agreement have been translated into directives that are found in a document called TB MED 230 (TB standing for "Technical Bulletin"). This is a joint publication of the Secretaries of the Army, the Navy, and the Air Force.

However, a complicating factor since the Seven Point Agreement was last published has been the Privacy Act of 1974. On occasion, misunderstandings about the specific provisions of the Act have impaired relations between officers at a domestic military base and the STD program in the State or local area. The problem usually centers around a perceived conflict between the obligation to report and a mandate to keep information confidential. In fact, there is no conflict. Official interpretations by legal arms of all branches of the Uniformed Services agree that reporting to civilian health authorities conforms to both the "Routine Use" and "Mandatory Disclosure" provisions of the Act. Note Exhibit 3 which appears toward the end of this Appendix. It is the

copy of a memorandum from the Office of The Surgeon General of the Air Force. Similar statements have been issued by the Surgeons General of the other branches. Finally, Exhibit 4 is a copy of Department of Defense Form 2005, a Privacy Act statement for signature of the military patient or a guardian. Note that paragraphs 3 and 4 expand upon the interpretation found in the memorandum in Exhibit 3.

- **Reporting and Other Cooperation by Veterans Administration Facilities**

Misunderstandings about the Privacy Act of 1974 also on occasion lead to a reporting impasse between an STD program and officials at a particular Veterans Administration medical facility. Again, in fact, no conflict exists at this time. A period of some official confusion in 1975 was clarified when Congress enacted Public Law 94-321 on June 29, 1976. This Act amended title 38, section 3301 of the United States Code to clarify the purposes for which a Veterans Administration facility official may release the names and/or addresses of present or former members of the uniformed services and their dependents. Excerpts of key passages from this Act are as follows:

> (f) The Administrator may....release the names or addresses or both of any present or former member of the Armed Forces, and/or their dependents....(2) to any.... instrumentality charged under applicable law with the protection of the public health or safety if a qualified representative of such agency or instrumentality has made a written request that such names or addresses be provided for a purpose authorized by law...

To comply with the Act, most project areas sent letters to their Veterans Administration factilities officially requesting reports and citing the applicable State statutes or local ordinances. In most places this letter was signed by the health officer or the health department epidemiologist because there were more than STD reports at stake. Such a letter should be on file at each Veterans Administration facility.

- **Freedom of Information Act (FOIA) — Applicability to Records of Grantees**

On occasion, an STD program will encounter someone who wants certain medical or disease intervention records and who cites the Freedom of Information Act (FOIA) as the basis for his or her demand. Such a demand is groundless, as affirmed by the United States Supreme Court in the case of Forsham v. Harris, Sup. Ct. No. 78-1118, 3/31/80. The FOIA is a Federal law which has limited application. State and local government agencies are not affected by it. In Forsham v. Harris, the Court held that the FOIA also does not require the Federal Government to obtain or release records held by a grantee. Specifically, the opinion of the Court states:

> Federal participation in the generation of data by means of a grant from HHS does not make the organization a federal 'agency' within the terms of the Act. Nor does this federal funding in combination with a federal right of access render the data 'agency records' of HHS which is a federal 'agency' under the terms of the Act.

- **Provisions of Contemporary Rape Legislation**

On October 28, 1978 the President signed Public Law 95-540 known as the Privacy Protection for Rape Victims Act of 1978. This law amended Article IV of the Federal Rules of Evidence by adding Rule 412 titled, "Rape Cases: Relevance of Victim's Past Behavior." Instead of being a trend setting piece of legislation, this Act merely reconciled the Federal Rules of Evidence with those in most States which had been similarly amended over the previous two years.

This legislation was intended to encourage rape victims to come forth, press charges, go to court, and testify against persons accused of rape. Its specific provisions include:

1. Reputation or opinion evidence about an alleged rape victim's past sexual behavior is not admissible in a rape/assault trial.

2. Evidence of the alleged rape victim's past sexual behavior, other than that related to reputation or opinion, may be admitted in a rape trial only if it is:
   a. evidence that persons other than the accused were the source of semen or injury, or
   b. evidence that the alleged victim consented to the sexual behavior from which the rape/assault resulted.
3. If the accused person has such evidence and intends to produce it, the court must be so informed in advance.
4. Before any such evidence is admitted, the court shall hold a hearing in chambers to determine whether the evidence is admissible.
5. If such evidence is admitted, the court will specify the areas of it upon which the alleged rape victim may be examined or cross examined.
6. Defines "past sexual behavior" to mean sexual behavior other than that from which the current rape/assault charges result.

This law denies defense attorneys their traditional method of impuning the credibility of an alleged rape victim. Other testimonial evidence also has been restricted. This creates enormous pressure to obtain physical evidence about the past sexual behavior of the alleged rape victim, for example, tapes, movies, and photos plus records of childbirth, abortion, and other medical conditions related to prior sexual activity.

The latter naturally includes STD medical and disease intervention records, plus the testimony of a D.I.S. who had conducted an interviewing/counseling session. Unfortunately, criminal rape cases tend to receive uncommon media attention and STD programs whose confidentiality statutes currently do not exempt records from subpoena are at serious risk of loosing public confidence in their guarantees of patient privacy.

Exhibit 1

(Agency Letterhead)

To: Postmaster
_____

Agency Control No. _____
Date: _____

Address Information Request

Please furnish this agency with the new address, if available, for the following individual or verify whether or not the address given below is one at which mail for this individual is currently being delivered. I the following address is a post office box, please furnish the street address as recorded on the boxholder's application form.

Name: _____

Last Known
Address: _____

I certify that the address information for this individual is required for the performance of this agency's official duties. I also certify that this request is made by an official public health agency pursuant to *confidential* activities related to the control of contagious diseases and therefore is exempt from the regular $1 fee as specified in Section B of POSTAL BULLETIN 21459, 5-24-84.

_____
(Signature of Agency Official)

_____
(Title)

For Post Office Use Only

[ ] MAIL IS DELIVERED TO ADDRESS GIVEN
[ ] NOT KNOWN AT ADDRESS GIVEN
[ ] MOVED, LEFT NO FORWARDING ADDRESS
[ ] NO SUCH ADDRESS
[ ] OTHER (SPECIFY): _____
_____

NEW ADDRESS
_____
_____

BOXHOLDER'S STREET ADDRESS
_____
_____

Agency Return Address

Postmark/Date Stamp

Exhibit 2

AFR 161-7 6 November 1969

SEVEN POINT AGREEMENT OF 1967

AN AGREEMENT ON MEASURES FOR THE CONTROL OF VENEREAL DISEASES

It is recognized that the following services should be developed by State and local health and law enforcement agencies in cooperation with the Public Health Service of the Department of Health, Education, and Welfare, the Coast Guard of the Department of Transportation, the Departments of the Army, Navy, and the Air Force of the National Defense and interested voluntary organizations:

1. The Armed Services and the Coast Guard will make consistent and continuous efforts to find venereal disease as it exists among military personnel; will provide early and definitive diagnosis to check foreign importation of venereal disease and to prevent its spread; will provide recommended treatment procedures to venereally infected military personnel; and will report all cases promptly to the State or local health departments concerned.

2. Health departments will provide adequate case-finding, diagnostic treatment, and follow-up procedures for the venereal diseases in the civilian population.

3. The civilian contacts of military personnel infected with venereal disease will be determined and reported by officers of the Armed Services and the Coast Guard through medical channels to State and/or local health authorities only.

4. The military contacts of infected civilians should be referred to medical officers of the Armed Services and the Coast Guard by local or State health authorities.

5. The law enforcement authorities are responsible for the repression of commercialized and clandestine prostitution. In order to limit the spread of venereal infections from these sources, the Armed Services and the Coast Guard will cooperate directly with law enforcement authorities in repressing prostitution and allied vice conditions.

6. An aggressive and continuous program of education shall be carried on among the civilian population, and a sound program of education about the venereal diseases shall be made a part of the training of all military personnel.

7. State and Territorial Health Officers, the Public Health Service of the Department of Health, Education, and Welfare, the Coast Guard of the Department of Transportation, and the Departments of the Army, the Navy, and the Air Force of the National Defense Establishment all urge the assistance of representatives of the American Social Health Association, affiliated social health societies, and of other official and voluntary welfare organizations or groups or responsible citizens in developing and stimulating public support for the above measures.

Robert S. McNamara
Secretary of Defense

John W. Gardner
Secretary of Health, Education, and Welfare

Alan S. Boyd
Secretary of Transportation

John H. Venable, M.D.
President
Association of State and Territorial Health Officers

Exhibit 3

DEPARTMENT OF THE AIR FORCE
HEADQUARTERS UNITED STATES AIR FORCE
BOLLING AFB DC 20332

REPLY TO ATTN OF: AFMSC SGPA BROOKS AFB TEXAS 78235

14 October 1983

SUBJECT: Communicable Disease Reporting and the Privacy Act

TO: ALMAJCOM-SOA/SG

1. Questions have been raised concerning the legality of Air Force medical treatment facilities (MTF) reporting communicable disease data, including patient names or personal identifiers, to state or local public health agencies in accordance with state or local laws. As required by AFR 168-4, para 12-131, Air Force MTFs do report communicable diseases to state or local authorities where required by law in order to cooperate with other governmental public health agencies in controlling communicable diseases. This reporting may include patient names or personal identifiers when required as part of the state or local public health agency's reporting system. Without such personal identifiers, public health agencies would be unable to monitor duplicate reporting (e.g. by multiple health care facilities) and would forfeit the ability to determine disease incidence accurately.

2. This practice does not violate the patient's rights under the federal Privacy Act, 5 U.S.C. 552a, because such disclosure is specifically authorized as a published routine use for health record information. This opinion has been coordinated with HQ USAF/JACM.

FOR THE CHIEF OF STAFF

GERALD W. PARKER, Brig Gen, USAF, MC
Director, Professional Services
Office of the Surgeon General

1st Ind, HQ SAC/SGPM, Offutt AFB NE 68113

8 NOV 1983

TO: AIG 671/SG/SGP/SGPM

Forwarded for your information and guidance.

ROBERT C. HAUVER, Colonel, USAF, MC, CFS
Director, Prof Svcs/Aerospace Medicine
Office of the Surgeon

Exhibit 4

Privacy Act Statement

Health Care Records

1. Authority for collection of information including social security number: Sections 113, 1071-87, 3012, 5031, and 8012, Title 10 US Code, and Executive Order 9397.

2. Principal purposes for which information is intended to be used: The purpose for requesting personal information is to assist medical personnel in developing records to facilitate and document your health condition in order to provide you health care treatment and to provide a complete account of such care rendered including diagnosis, treatment and end result. The SSN is necessary to identify the person and records.

3. Routine uses: This information may be used to plan and coordinate health care. It may be used to provide medical treatment, conduct research, teach, compile statistical data, determine suitability of persons for service or assignments; implement preventive health and communicable disease control programs; adjudicate claims and determine benefits; evaluate care rendered; determine professional certification and hospital accreditation; conduct authorized investigations; provide physical qualifications of patients to other federal, state and local agencies upon request in the pursuit of their official duties and report medical conditions required by law to federal, state, and local agencies. It may be used for other lawful purposes including law enforcement and litigation.

4. Whether disclosure is mandatory or voluntary and effect on individual of not providing information: In the case of active duty military personnel, disclosure of requested information is mandatory; in the case of all other personnel/beneficiaries, disclosure of requested information is voluntary. If the information is not furnished, optimum medical care may not be possible.

I understand that the foregoing one time privacy act statement will apply to all request for personal information made by medical treatment personnel or for medical treatment purposes. I further understand that a copy of this form which I have signed will be placed in my health care records as evidence of this notification. I have received a copy of this statement which I can retain, and I understand that I can receive additional copies of this statement from any medical treatment facility upon request.

_____

Signature of Parent (or authorized sponsor or guardian of Patient)

Date Signed _____

DD Form 2005
1 Sep 75

Appendix H

Summary of STD Control Program Operations Standards

I. INTRODUCTION

- A quality assurance system for all appropriate components that support disease intervention is established and maintained.
- Acceptable levels of productivity from each control component, and the qualitative standards of performance expected to produce them, are clearly specified by program management.
- A data collection system is established and maintained to provide current data for operational decision making.

II. PROGRAM MANAGEMENT

- *Outcome objectives* address the 1990 Objectives for the Nation.
- *Impact objectives* address each program component as defined in grant guidelines, and are clearly stated, realistic, specific, measurable, and time-phased.
- *Process objectives* are realistic, specific, measurable, time-phased, and clearly relate to the achievement of program impact objectives.
- The operational plan clearly explains how the impact objectives and the process objectives of the program will be achieved.
- The operational plan is revised when problems result in unsatisfactory achievement of any established impact or process objectives or when improved methods are devised to pursue particular objectives.
- The STD program establishes and maintains a system for evaluation of its intervention efforts.
- The evaluation plan clearly describes the procedures for gathering outcome and process performance information and the systems for reporting to program management.
- The evaluation plan clearly describes how outcome and performance information are used to provide quality assurance for various program activities.
- The program has a system to assure ongoing interaction with all agencies which can impact on STD control.
- When non-STD health care needs of patients are identified, the program establishes referral arrangements with appropriate service providers that collaborate with the program in STD control activities.

III. GONORRHEA SURVEILLANCE

- The project area supports and promotes a system for the detection of asymptomatic gonococcal infections among women of reproductive age.
- The program maintains a system to assure that treatment is provided to infected women identified through this screening process.
- The program maintains a mechanism for assessing disease trends among sexually active women to compare with the trends from public STD clinics.
- The gonorrhea screening component includes:
  - a system to regularly analyze screening results by individual provider sites;
  - periodic, documented on-site observations to assure all procedures are functioning at an optimum level;
  - periodic, documented firsthand observations of the performance of the culture delivery system; and,
  - periodic data produced by laboratory quality control procedures.
- Each program will establish a data system which allows for the analysis of screening data both by individual site, type of provider, and in the aggregate.
- All decisions affecting the scope and composition of the gonorrhea screening program are based upon the output data *and* the documented firsthand observations of process quality at individual sites.

- Each health care provider offering treatment is systematically encouraged to reculture treated female gonorrhea patients 3 to 7 days after completion of therapy.

IV. RESISTANT GONORRHEA

- The STD program establishes and maintains all the surveillance, laboratory, and disease intervention outreach systems necessary to identify and abort any outbreaks of PPNG, CMRNG or other resistant strains of *N. gonorrhoeae*.
- The program establishes an incidence threshold for recommending that all gonorrhea patients be routinely treated with recommended therapy for resistant organisms.
- The STD program ensures that the following categories of patients receive both an anogenital culture for gonorrhea, which includes testing for penicillin resistant and β-lactamase producing organisms, and appropriate therapy for resistant organisms:
  - sex partners and/or clusters to a PPNG or CMRNG case;
  - patients with a history of travel (within 60 days) to foreign or domestic areas of high-prevalence;
  - treatment failures confirmed by positive laboratory results.
- The STD program has a system which ensures that the sex partners of PPNG and CMRNG patients are rapidly identified, medically evaluated, appropriately tested and adequately treated.

V. CHLAMYDIA CONTROL ACTIVITIES

- The STD control program establishes a surveillance system to identify the extent and trend of *C. trachomatis* infections within its jurisdiction.
- The STD program establishes a high risk profile which delineates those patients who should receive dual therapy to cover both chlamydial and gonococcal infections.
- The STD program establishes a system which ensures all high risk patients seen in STD clinics are counseled to refer their sex partners for medical evaluation.
- The STD program establishes a system which ensures that each PID patient receives an interview/counseling session by a D.I.S.

VI. PELVIC INFLAMMATORY DISEASE

- A system to culture and follow identified PID is established and maintained.
- Ensure that recommended procedures are observed, and possible cases are screened and followed by regularly visiting PID screening sites.
- The program establishes a system to ensure that patients diagnosed with PID are assessed within 5 days of their initial visit.
- The program establishes a system which ensures that all patients diagnosed with PID and those providing care for them are aware of the need to have a test-of-cure culture performed within 3 to 7 days following completion of therapy.
- The program establishes a cooperative system in which hopitals and other PID surveillance sites assume increasing responsibility to conduct initial PID patient counseling, search records, verify laboratory results, ensure medical assessment and test-of-cure referrals, and, *especially*, to make prompt referrals of patients to the health department for an interviewing/counseling session by a D.I.S.
- The program establishes a system to provide regular feedback to hospitals and other PID surveillance sites about cases identified, including results of case investigation activities.
- The program should assertively pursue the ideal of a PID initiative where D.I.S. involvement in each case begins with an interviewing/counseling session conducted with a patient successfully referred to the clinic by a diagnosing facility.
- The program establishes and maintains a system which ensures that the infected sex partners of PID patients are rapidly identified and treated.

VII. SYPHILIS SURVEILLANCE

- The program has an efficient, up-to-date central registry which includes the following:
  - Patient name
  - Last address
  - Age or birth date
  - Race/ethnic origin
  - Sex
  - Diagnosis
  - Date and result of all positive tests
  - Treatment date(s) & regimen
  - Health provider of record
- The program has written criteria that clearly states which reactors are administratively closed (usually because of age, titer, or negative confirmatory test), which reactors will receive followup, the method for doing so, and who has responsibility in each situation.
- The program establishes a policy to routinely assess yield from age/titer categories to effectively differentiate between high and low priority STS and to decide which should receive administrative closure.
- The program has a legal requirement that all reactive STS are reported.
- The program has a system to monitor reactive STS reporting by individual laboratories.
- The program has a quality assurance system which, either by letter or visitation on at least an annual basis, confirms the reporting performance of all medical laboratories performing tests for STD.
- At least annually, the program distributes summary reactor reporting and followup results data to all medical laboratories.

VIII. STD INTERVENTION ACTIVITY

- The program develops and publishes process performance standards for disease intervention outreach activities.
- The program maintains systems to keep management informed of the yield from disease investigation activities.
- The program establishes and maintains a D.I.S. quality assurance system that keeps management regularly informed about the quality of individual D.I.S performance.
- The program maintains a system to ensure that all employees' formal performance evaluations accurately reflect the quality of their performance and the program impact which results from that performance.
- The program has a system which ensures that before any original interviewing/counseling session, the D.I.S. undertakes a thorough analysis of:
  - available medical records;
  - available historical information pertinent to the current infection;
  - interviewing/counseling and investigative records for evidence of relationships to other known cases; and,
  - information from other D.I.S. staff.
- To achieve maximum disease intervention, STD interview/counseling sessions are conducted without delay after the case comes to program attention to:
  - clarify to the patient the health department's responsibility for interrupting disease transmission and the department's professional, confidential methods for ensuring that all sex partners receive prompt examination and necessary treatment;
  - give sound justification for discussing the detailed specifics about each sex partner or any other persons who need an STD examination;
  - positively, but assertively, confront the patient about any evasive behavior that suggests indifference toward curing his/her own infection or which might jeopardize the health of sex partners;

- ensure through tactful persistence that each sex partner at-risk is discussed and then described in the detail necessary to affect the promptest possible examination.
- set conditions of referral whenever it is agreed that the patient will refer a sex partner for examination;
- provide understandable information to the patient about his/her disease; and,
- counsel on appropriate behaviors to ensure the patient's present disease is cured, that the risk of future disease is minimized, and that, if infected again, the patient will present for medical evaluation and treatment as soon as possible.

- Immediately after all interviewing/counseling sessions (including reinterviews and cluster interview), the D.I.S. thoroughly:
  - searches for information on sex partners to determine any prior medical or disease intervention records relevant to the present case;
  - reviews standard investigative resources to confirm locating information on all sex partners;
  - analyzes the disease intervention information on identified sex partners and accurately determines probable relationships, possible factual omissions, and potential avenues to pursue future disease intervention.
  - determines the need for reinterviews and/or cluster interviews or decides to discontinue further activities.
- A reinterview is considered only after an assessment establishes a high probability that it will produce disease intervention. Such assessment should include the following:
  - review of all pertinent records, reports and notes from the original interviewing/counseling session concerning factual omissions or unresolved patient problems;
  - the current status and results of sex partner referrals; and,
  - the identification of epidemiologic relationships, the existence of a potential source, and in particular, any suggestion of nondiscussed sex partners during the period the patient was infectious.
- To successfully achieve disease intervention, STD reinterviews are conducted in such a manner that each patient is:
  - seen reasonably soon after the original interviewing/counseling session (as soon as the last key item of readily accessible disease intervention information is available for analysis and planning, and certainly no longer than 10 days),
  - approached with a purpose and is tactfully led through a discussion planned on the basis of an analysis of available information and a judgment about its possible meaning; and,
  - positively, but assertively, confronted concerning any evasive behavior regarding the referral of sex partners or the treatment or followup of his/her recent infection.
- Persons who receive a cluster interview are:
  - selected on the basis of a reasoned judgment that they are likely to contribute information of disease intervention value for priority STD cases;
  - selected on the basis of a reasoned judgment that the index patient's exposure information is so questionable that to accept it without confirmation may result in the inappropriate provision or withholding of preventive treatment; and,
  - approached with an agenda developed from a thorough analysis of all available disease intervention information.
- To successfully achieve disease intervention or to obtain information which will advance it, STD cluster interviews are conducted such that each individual is:
  - given no information by the D.I.S. which would confirm that any specific sex partners or friends have disease, had disease, were exposed to disease, or received an examination for disease;
  - given logical reasons to conclude that it is in his/her personal interest to discuss his/her sex partners and the behavior of others to reduce the risk of disease in his/her sociosexual group; and,
  - provided easily understood information about the disease to which he/she has been exposed and logical, acceptable ways to avoid similar risk in the future.
- The program establishes and maintains a system which ensures that each work document is legible and initiated and processed in accordance with prescribed procedures.

- The program establishes and maintains a system to ensure that each initiated work document is completed within specified time requirements.
- The program establishes and maintains a system to ensure that each disease intervention outreach activity work record is:
  - legibly, coherently, and accurately documented to permit the rapid reconstruction of all activities performed; and,
  - documented in timely fashion so that all open and active investigation records reflect the most current activity performed.
- Program management clearly specifies acceptable levels of productivity and qualitative standards for direct followup activity and maintains accountability of staff for meeting them.
- The STD program has written policies indicating which patients may be indirectly referred and the time frames in which the referrals must be made.
- The STD program has a strictly monitored system to ensure prompt program intervention when indirect referral contracts are broken or do not succeed within the agreed time frames.

IX. STD OUTBREAK CONTROL INITIATIVE

- The need for an outbreak control initiative is clearly defined by a formal STD control status assessment using epidemiologic principles and procedures and a comprehensive analysis of data.
- The preparation for an outbreak control initiative includes a thorough assessment of recent and current activity, the preparation of individual cases with detailed instructions, and the establishment of an efficient basic filing system.
- The preparation for an outbreak control initiative includes a review of the core STD clinic and a needs assessment of D.I.S. and skill development and use and any indicated arrangements for formal training as described in the "Quality Assurance Guidelines for Managing the Performance of Disease Intervention Specialists in STD Control."
- The organization of an outbreak control initiative includes goals, action plans, timetables, and materials, plus the precise definition and clear communication of individual responsibilities to everyone involved.
- Each outbreak control initiative includes an evaluational component which is sufficiently precise to detect problems, permit immediate adjustments, and accurately signal when to terminate activities based on predetermined goals or changes in the situation and/or factors of cost.
- Any program manager without prior experience in planning and implementing an outbreak control initiative actively seeks support and assistance from DSTD, CDC.

IX. ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)

- Persons receiving various STD clinical and disease intervention services who possibly have been exposed to the HTLV-III virus are counseled regarding their risk of infection with the virus and behavioral options that may reduce this risk.
- All STD program staff members involved in AIDS/HTLV-III infection health promotion and risk reduction counseling activities are periodically observed by appropriate supervisors to ensure that accurate and consistent messages are being delivered in a sensitive manner and that all questions are being answered accurately.
- STD program HTLV-III antibody testing services are structured to ensure maximum confidentiality for all persons tested and counseled.
- All STD program staff conducting pretest and posttest counseling activities related to HTLV-III antibody testing have their performance periodically observed by a firstline supervisor to ensure that the information conveyed is consistent, accurate, and delivered in the most sensitive manner possible.
- STD program management ensures that a network of medical and mental health professionals is established to permit counseling staff to smoothly effect referrals and to minimize the problems which patients encounter in receiving the necessary services.

X. CHILD ABUSE

- The program will establish and implement a formal written policy for handling suspected child abuse. This policy should include:
  - procedure for reporting of suspected cases,
  - referral procedure for children, and
  - procedure for interviewing/counseling and followup or total referral to staff responsible for arranging child abuse cases.

XI. LEGAL AUTHORITIES FOR STD CONTROL

- Each State has a complete set of legal authorities (statute or regulation with statutory authority), which includes the following:
  - definitions of diseases to be controlled, including morbidity reporting by name, address, disease, sex, age, race and source of report;
  - confidentiality of STD records to the maximum extent legally possible including exemption from subpoena (statutory and common law case precedents for which are available from the Division of Sexually Transmitted Diseases, Centers for Disease Control);
  - prenatal serologic testing to include at least one serologic test during both the first and third trimester of pregnancy;
  - ophthalmia neonatorum prophylaxis;
  - venipuncture by field staff;
  - laboratory reporting of positive tests to include time frames, name of physician; patient's name, age, race, sex, tests performed and test results; and,
  - STD education in public schools to ensure STD information is taught uniformly as part of the public school curriculum.
- Each program has a system to ensure that such laws are reviewed and revised, if necessary.

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